December 1, 2023

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

Re: K231057
Trade/Device Name: Antibacterial Gel Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 26, 2023
Received: May 26, 2023

Dear Yeqing Cai:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,
Yu-chieh Chiu -S
Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231057

Device Name
Antibacterial Gel Wound Dressing

Indications for Use *(Describe)*

For Prescription Use:
Under the supervision of a healthcare professional, Antibacterial Gel Wound Dressing is indicated for the management of first and superficial second degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

For Over-the-Counter Use:
Antibacterial Gel Wound Dressing is intended for the management of minor abrasions, cuts, lacerations and scalds.

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

The assigned 510(k) Number: K231057

1. Date of Submission: April 13, 2023

2. Submitter Identification

Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, Shenzhen City, Guangdong Province, 518109, China

Contact Person: Yeqing Cai
Position: Regulatory Affairs Specialist
Tel: +86-755 28138888
Fax: +86-755 28134588
Email: 152323 @winnermedical.com

3. Identification of Subject Device

Trade/Proprietary Name: Antibacterial Gel Wound Dressing
Device Common Name: Dressing, Wound, Drug
Classification: Unclassified
Product Code: FRO
Review Panel: General & Plastic Surgery

4. Identification of Predicate Device

Predicate Device:
AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B (K083103)
Manufacturer: AcryMed, InC.

5. Device Description

The subject device, Antibacterial Gel Wound Dressing, is a non-sterile, repeated-use moist amorphous gel. The hydrogel consists of amorphous cellulose-based gel complex, silver ions and Benzalkonium Chloride (BZK). The silver ions and Benzalkonium Chloride (BZK) act as a preservative to inhibit the growth of microorganisms in the gel during shelf storage. The hydroxyethyl cellulose is used as thickener to modify the viscosity of the wound gel, resulting in

a moist amorphous gel with the function of moisture donation and moisture absorption. The combination of allantoin and propylene glycol are used as moisturizer to prevent gel water release. The gel possesses both moisture donating and moisture sequestering action depending on the moisture level in the wound. The hydrogel helps to maintain a moist wound environment. The hydrogel is supplied in collapsible blind ended heat sealed HDPE tubes fitted with screw caps.

6. Intended Use Statement

Antibacterial Gel Wound Dressing is intended for prescription (Rx) and over-the-counter (OTC) use as follows:

- For Prescription Use:

Under the supervision of a healthcare professional, Antibacterial Gel Wound Dressing is indicated for the management of first and superficial second degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

- For Over-the-Counter Use:

Antibacterial Gel Wound Dressing is intended for the management of minor abrasions, cuts, lacerations and scalds.

7. Substantially Equivalent (SE) Comparison

The subject device, Antibacterial Gel Wound Dressing, is compared with the following predicate device in terms of intended use, material components, technology, performance and etc. The data of the predicate device from commercially product labeling and 510(k) summary is as following.

- Predicate Device, K083103, AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B, Manufactured by AcryMed, InC.

Device Characteristic	Subject device K231057	Predicate device K083103
Product Code	FRO	FRO
Class	Unclassified	Unclassified
Intended Use	**For Prescription Use:** Under the supervision of a healthcare professional, the Antibacterial Gel Wound Dressing is indicated	**For Prescription use:** Under the supervision of a healthcare professional, AcryDerm Silver Antimicrobial Wound Gel Model #B

	for the management of first and superficial second degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites. **For Over-the-Counter Use:** Antibacterial Gel Wound Dressing is intended for the management of minor abrasions, cuts, lacerations and scalds.	is indicated for the management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites. **For Over-the-Counter Use:** AcryDerm Wound Gel Model #B is indicated for the management of minor abrasions, cuts, lacerations and scalds.
Material Components	Hydroxyethyl cellulose, propylene glycol, allantoin, silver ions, benzalkonium chloride and purified water;	Water, hydrophilic polyacrylate absorbent microspheres, stabilized silver salt;
Technological Characteristics	The Antibacterial Gel Wound Dressing is applied directly on wound site to control wound moisture levels through dual function of moisture donation and absorption. The gel contains silver ions and Benzalkonium chloride acting as a preservative for reducing microorganism colonization within the dressing during the shelf storage.	The AcryDerm Antimicrobial Silver Gel Wound Dressings incorporate proprietary stabilized silver salt to facilitate the action of antimicrobial ionic silver in the dressing and wound environment. The gel possesses both moisture donating and moisture sequestering action depending on the moisture level in the wound.
Antimicrobial Agent	silver ions and Benzalkonium chloride	Stabilized silver salt
Preservative Effectiveness	USP <51>	USP <25>
Single use or Repeated use	Repeated use for a single patient	Repeated use for a single patient
Sterilization	Non-sterile	Non-sterile
Biocompatibility	Comply with ISO 10993-5, ISO 10993-10, ISO 10993-6 and ISO 10993-11.	Comply with ISO 10993-1.

8. Substantial Equivalence Discussion

Antibacterial Gel Wound Dressing has been subjected to ISO 10993 biocompatibility studies to demonstrate the device is as safe as its predicate device. The performance tests were conducted to demonstrate that the subject device is as effective as its predicate device.

Performance Testing

The following table summarized performance tests conducted on subject devices in comparison to the predicate device:

Performance Test	Standard	Subject device Result
Fluid Affinity	EN 13726-1 Test methods for primary wound dressings - Part 1: Aspects of absorbency	Moisture Donation ＞15-20% Moisture Absorption 0-10%
Loss on Drying	USP <731> Loss on Drying	90%±2%
pH Value	USP <791> pH	5.5-7.5
Bioburden	USP <61> Microbiological examination of non-sterile products-microbial enumeration tests; USP <62> Microbiological examination of nonsterile products-tests for specified microorganisms	Pass
Preservative Effectiveness	USP <51> Antimicrobial Effectiveness Testing	Pass

Biocompatibility Testing

Biocompatibility testing was conducted for this submission in accordance with the US Food and Drug Administration's guidance entitled Use of International Standard ISO‐10993: 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' and test results meet the requirements.

Animal Study

A porcine wound healing study was carried out to evaluate the cytotoxicity of subject device. The study demonstrated that there were no biologically relevant differences between the subject

devices (Antibacterial Gel Wound Dressing), and a Control Silver Antimicrobial Wound Gel (also named SILVASORB GEL®) in terms of wound healing performance characteristics.

Clinical Study

No clinical study was conducted.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison analysis, performance tests, biocompatibility tests and animal study provided in this submission, the subject device, Antibacterial Gel Wound Dressing is demonstrated to be as safe and effective as the legally marketed predicate devices, AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B (K083103). So, the subject device is considered Substantially Equivalent (SE) to the predicate device.