January 13, 2023

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

Re: K221755
Trade/Device Name: Antimicrobial gauze sponge dressing; Antimicrobial super sponge dressing; Antimicrobial non-woven sponge dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 15, 2022
Received: December 15, 2022

Dear Mingni Liu:

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 and Part 809 **)**; 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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221755

Device Name
Antimicrobial gauze sponge dressing; Antimicrobial super sponge dressing; Antimicrobial non-woven sponge dressing

Indications for Use *(Describe)*
Antimicrobial gauze sponge dressing, antimicrobial super sponge dressing, and antimicrobial non-woven sponge dressing are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, 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."*

# Tab#7 510(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: K221755

1. Date of Preparation: June 08, 2022

2. Sponsor 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: Mingni Liu
Position: RA Engineer
Tel: +86-755 28138888-8822
Fax:+86-755 28134588
Email:2346@winnermedical.com

3. Identification of Proposed Device

Trade Name:
Antimicrobial gauze sponge dressing (OTC)
Antimicrobial super sponge dressing (OTC)
Antimicrobial non-woven sponge dressing (OTC)

Regulatory Information

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

Indications for use:

Antimicrobial gauze sponge dressing, antimicrobial super sponge dressing, and antimicrobial non-woven sponge dressing are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.

Device Description-

The devices are available in three configurations, which are Antimicrobial gauze sponge dressing, Antimicrobial super sponge dressing and Antimicrobial non-woven sponge dressing. All of them consist of (1) a dressing (base material) and (2) anti-microbial agent. For each configuration, it is available in several models, which are different in size and quantity of anti-microbial agent.

Based on in vitro testing, the product can achieve board spectrum antimicrobial effect within the dressing for Gram+ and Gram- Bacteria and Fungi. It has been shown to have 4 log bacterial reduction in vitro against the following test organisms: Staphylococcus aureus (ATCC 6538), Escherlchia coli (ATCC 25922), Candida albicans (ATCC 10231), Pseudomona aeruginosa (ATCC 9027) and Bacillus subtilis (ATCC 6633), Streptococcus pyogenes (ATCC 19615), Serratia marcescens (ATCC 31026), Aspergillus niger (ATCC 16404). The effective inhibition of bacteria is 7 days.

5. Identification of Predicate Device

Primary Predicate Device
510(k) Number: K181315
Product Name:
Antimicrobial gauze sponge dressing
Antimicrobial super sponge dressing
Antimicrobial non-woven sponge dressing

Secondary Predicate Device
510(k) Number: K070653
Product Name: Kendall Kerlix AMD Antimicrobial Gauze Dressing (OTC)

The Antimicrobial gauze sponge dressing (OTC)/ Antimicrobial super sponge dressing(OTC)/ Antimicrobial non-woven sponge dressing(OTC) for OTC use is substantially equivalent in intended use, function, and composition to Antimicrobial gauze sponge dressing/ Antimicrobial super sponge dressing/ Antimicrobial non-woven sponge dressing (Rx) cleared by FDA under 510(k) No. K181315. The primary purpose of this 510(k) is to allow OTC retail marketing of this dressing. Labeling of the OTC product has been revised to include added directions for use for a non-professional retail population.

6. 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. Since the proposed device has the same device design as the primary predicate device, the tests performed for the primary predicate device can be leveraged for the proposed device. These tests including: cytotoxicity, skin sensitization, irritation, acute systemic toxicity, pyrogen, implantation and subacute systemic toxicity, bacterial endotoxin, antimicrobial effectiveness test, EO ECH residue test.

The performance test, including antimicrobial effectiveness test and liquid absorbency test were conducted on the proposed 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 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals.
- ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- ISO 10993-11:2006 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

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

| Item | Proposed Device | Primary Predicate Device K181315 | Secondary Predicate Device K070653 |
|---|---|---|---|
| Product Code | FRO | FRO | FRO |
| Regulation Number | NA | NA | NA |

| | | | |
|---|---|---|---|
| Intended Use | Antimicrobial gauze sponge dressing (OTC), antimicrobial super sponge dressing (OTC), and antimicrobial non-woven sponge dressing (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns. | The Antimicrobial gauze sponge dressing / Antimicrobial super sponge dressing / Antimicrobial non-woven sponge dressing are intended to use as primary or secondary dressings for exuding wounds, surgical incisions, lacerations, abrasions, first and second degree burns, wound packing, donor sites, catheter sites, I.V. sites and central lines. Also may be used for securement of primary dressing. The antimicrobial activity of the PHMB and benzalkonium chloride in dressing helps resist bacterial colonization within the dressing. | The Kendall Kerlix AMD Antimicrobial Gauze Dressing is intended for OTC use. It is used as a primary dressing for exuding wounds, burns, as a cover for surgical wounds, and to secure and prevent movement of primary dressings. |
| Single Use | Yes | Yes | Yes |
| Antimicrobial | Polyhexamethylene Biguanide HCl (PHMB) Benzalkonium chloride (BKC) | Polyhexamethylene Biguanide HCl (PHMB) Benzalkonium chloride (BKC) | Polyhexamethylene Biguanide HCl (PHMB) |
| Antimicrobial Time | 7 days | 7 days | Unknown |
| Sterilization | EO Sterilization | EO Sterilization | EO Sterilization |
| SAL | $10^{-6}$ | $10^{-6}$ | $10^{-6}$ |
| Material | Gauze rolls / Fluff gauze rolls / Non-woven, Polyhexamethylene Biguanide HCl (PHMB) Benzalkonium chloride (BKC) | Gauze rolls / Fluff gauze rolls / Non-woven, Polyhexamethylene Biguanide HCl (PHMB) Benzalkonium chloride (BKC) | Gauze rolls / Fluff gauze rolls / Polyhexamethylene Biguanide HCl (PHMB) |
| Biocompatibility | Comply with ISO 10993-5, ISO 10993-10, ISO 10993-6 and ISO 10993-11. | Comply with ISO 10993-5, ISO 10993-10, ISO 10993-6 and ISO 10993-11. | Comply with ISO 10993-1 |

9. 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.