February 14, 2019

Winner Medical Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 China

Re: K181315
Trade/Device Name: Antimicrobial gauze sponge dressing, Antimicrobial super sponge dressing, Antimicrobial non-woven sponge dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 4, 2019
Received: January 7, 2019

Dear Diana 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -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)*
K181315

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

Indications for Use *(Describe)*
It is intended for 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.

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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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: K181315

1. Date of Preparation: 04/08/2018

2. Sponsor Identification

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

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Antimicrobial gauze sponge dressing
Antimicrobial super sponge dressing
Antimicrobial non-woven sponge dressing

Regulatory Information

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

Indications for Use Statement:

It is intended for 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.

Device Description

The proposed 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.

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 includes: Staphylococcus aureus, Escherlchia coli, Candida albicans, Pseudomona aeruginosa and Bacillus subtilis, Streptococcus pyogenes, Serratia marcescens, Aspergillus niger. The effective inhibition of bacteria within the dressing is 7 days.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K160872
Product Name: PolyPlex Wound Dressing

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. 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.
- SO 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 K181315	Predicate Device K160872
Product Code	FRO	Same
Regulation Number	NA	Same
Intended Use	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.	Under the management of a healthcare professional, Poly Plex Wound Dressing is intended for the management of first and second degree bums, venous stasis ulcers, diabetic ulcers, partial and full thickness wounds, donor sites, post surgical incisions, trauma wounds, and abrasions. It can be used during wound dressing changes to soften encrusted wound dressings .
Single Use	Yes	Yes

Antimicrobial	Polyhexamethylene Biguanide HCl (PHMB) Benzalkonium chloride (BKC)	Same
Sterilization	EO Sterilization	Unknown
SAL	10^{-6}	Unknown
Material	Gauze rolls / Fluff gauze rolls / Non-woven rolls, Polyhexamethylene Biguanide HCl (PHMB) Benzalkonium chloride (BKC)	petrolatum-based emulsion, Polyhexamethylene Biguanide (PHMB) Benzalkonium Chloride (BZK)
Biocompatibility	Comply with ISO 10993-5, ISO 10993-10, ISO 10993-6 and ISO 10993-11.	Comply with ISO 10993

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.