June 21, 2023

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

Re: K221311
Trade/Device Name: Antibacterial Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 29, 2022
Received: May 5, 2022

Dear Yi Fu:

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,

David Krause -S

for Julie A. 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)*
K221311

Device Name
Antibacterial bandage

Indications for Use *(Describe)*
Antibacterial bandage is to be applied topically to the skin for management of minor cuts, minor scrapes 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 is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K221311

1. **Date of Preparation**: June 14, 2023

2. **Submitter Identification**

Winner Medical Co., Ltd.

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3. **Identification of Subject Device**

Trade/Proprietary Name: Antibacterial Bandage
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: K113583
Product Name: Curad Antibacterial Bandage
Manufacturer: Medline Industries, Inc

Reference Device:
510(k) Number: K200821
Product Name: Anti-bacterial Bandage
Manufacturer: Planet (Suzhou) Medical Product Co., Ltd

5. Device Description

The subject device, Antibacterial bandage, is to be applied topically to the skin for the management of minor cuts, minor scrapes and minor burns.

The subject devices are available sterile in three models. All of devices contain three layers: (1) adhesive backing layer (fabric or plastic); (2) exactly same antibacterial non-stick absorbent pad layer (composed of Polyester fiber, viscose fiber, PE mesh, Benzalkonium chloride); (3) release liner.

Each model is available in different sizes with identical materials, chemicals and physical properties, therefore, size of the device will not affect the function and performance of products.

All models of subject device, Antibacterial bandage, are for single use only and sterilized by Ethylene Oxide using conditions validated following ISO 11135:2014.

6. Intended Use/Indications for Use

Antibacterial bandage is to be applied topically to the skin for management of minor cuts, minor scrapes and minor burns.

7. Substantially Equivalent (SE) Comparison

The subject device, Antibacterial Bandage, is compared with the following Predicate Device in terms of intended use, materials, principle of operation, characteristics and performance. The predicate device is K113583, Curad Antibacterial Bandage, Manufactured by Medline Industries, Inc. The reference device is K200821, Anti-bacterial Bandage, Manufactured by Planet (Suzhou) Medical Products Co., Ltd.

The following table shows comparison between subject device and predicate device and reference device. Based on the comparison and analysis, the subject devices are determined to be Substantially Equivalent (SE) to the predicate device. These data came from commercially product labeling and 510(k) summary.

Table 1. Comparison of Intended use, Design and Technological Characteristics

Item	Subject Device (K221311)	Predicate Device (K113583)	Reference Device (K200821)
Product Code	FRO	FRO	FRO
Regulation Number	Unclassified	Unclassified	Unclassified
Device Classification Name	Dressing, wound, drug	Dressing, wound, drug	Dressing, wound, drug
Intended Use	Antibacterial bandages are to be applied topically to the skin for management of minor cuts, minor scrapes and minor burns.	Antibacterial bandages are to be applied topically to the skin to help prevent infection in minor cuts, scrapes and minor burns.	Anti-bacterial bandages are to be applied topically to the skin for management of minor cuts, minor scrapes.
Components	(1) Adhesive backing layer; (2) Antibacterial non-stick absorbent pad layer; (3) Release liner;	(1) Adhesive backing layer; (2) Antibacterial non-stick absorbent pad layer; (3) Release liner;	(1) Adhesive backing layer; (2) Antibacterial non-stick absorbent pad layer; (3) Release liner;
Principle of operation	Benzalkonium chloride in the absorbent pad is to reduce bacterial colonization within dressing, Backing adhesive layer for self-adhesive and keep the bandage in place.	Backing adhesive layer for self-adhesive and keep the bandage in place.	Benzalkonium chloride reduce bacterial colonization within dressing, Backing adhesive layer for self-adhesive and keep the bandage in place.
Technology	Center non-woven absorbent pad is impregnated with benzalkonium chloride	Center non-woven absorbent pad is impregnated with benzalkonium chloride	Center non-woven absorbent pad is impregnated with benzalkonium chloride
Antimicrobial agent	0.8% (w/w) benzalkonium chloride	0.8% (w/w) benzalkonium chloride	0.1%/0.8% (w/w) benzalkonium chloride
Antibacterial Effectiveness	≥4 Log reduction	≥4 Log reduction	≥4 Log reduction
Characteristics	• Sterile • Soft non-stick absorbent pad as wound contact layer • Absorbs wound exudates	• Sterile • Soft non-stick absorbent pad as wound contact layer • Absorbs wound exudates	• Sterile • Soft non-stick absorbent pad as wound contact layer • Absorbs wound exudates

	• Antibacterial bandage contains benzalkonium chloride that reduce bacterial colonization within dressing • Backing layer with adhesive for self-adhesive	• Backing layer with adhesive for self-adhesive	• Antibacterial bandage contains benzalkonium chloride that reduce bacterial colonization within dressing • Backing layer with adhesive for self-adhesive
Sterilization	Ethylene Oxide Sterilization	Ethylene Oxide Sterilization	Ethylene Oxide Sterilization
Single-use	Yes	Yes	Yes
Biocompatibility	Complies with ISO 10993-1 for limited contact duration on breached/compromised skin	Comply with ISO 10993	Comply with ISO 10993

8. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the subject device met all design specifications was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the corresponding standards.

Performance Test

Following performance tests were conducted on the subject device in comparison to the predicate device. The test results demonstrated that the performance characteristics of the subject device met the requirement and supported substantially equivalence between the subject device and the predicate device.

- Liquid absorbency: EN 13726-1:2002 Test methods for primary wound dressing – Part 1 Aspects of absorbency
- Moisture vapor transmission rate: EN 13726-2:2002 Test methods for primary wound dressing – Part 2 Moisture vapor transmission rate of permeable film dressing
- Peel strength: ASTMD3330/D3330M Standards peel adhesion of pressure-sensitive tapes
- Antibacterial effectiveness: Modified AATCC 100 Test Method for Antibacterial Finishes on Textile Materials

The sterile barrier package testing was performed on the subject device and the test results demonstrated that the subject device package can maintain its integrity.

- 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.

Biocompatibility Tests

The biocompatibility evaluation for the subject device was conducted in accordance with the ISO 10993-1:2018 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process"

The biocompatibility tests include: Cytotoxicity, Skin sensitization, Irritation. Systemic toxicity and Material mediated pyrogenicity test.

The tests were conducted following these 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 10993-11:2017 Biological Evaluation Of Medical Devices- Part 11: Tests For Systemic Toxicity.
- USP 151:2017 Pyrogen Test
- USP-NF:2021 <85> Bacterial Endotoxins Test

Animal Studies

A porcine wound healing study was carried out to evaluate the cytotoxicity of the subject device. The study demonstrated that there was no difference between the Test—Antibacterial Bandage (subject device), and a Control—Curad Antibacterial Bandage (predicate device) in terms of wound healing performance characteristics and local tolerance after wound creation.

Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

The subject device Antibacterial Bandage is compared to the predicate device with respect to intended use, materials, principle of operation, characteristics and performance. According to the comparison information, most of the characteristics are the same, the material components between subject device and predicate device shows slightly different, but none of them will cause new safety or effectiveness issues. Based on the comparison and analysis, the subject device is determined to be Substantially Equivalent (SE) to the predicate device.