February 5, 2021

Jiangsu Excellence Medical Supplies Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K201324
Trade/Device Name: Antibacterial Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 4, 2021
Received: January 5, 2021

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/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
Assistant Director (Acting)
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)*
K201324

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: K201324

1. Date of Preparation: February 5, 2021

2. Sponsor Identification

Jiangsu Excellence Medical Supplies Co., Ltd.
No.65 Huiling West Road, Zouqu Town, Zhonglou District, Changzhou City, Jiangsu Province, 203144, China

Establishment Registration Number: 3010138147

Contact Person: Yanhua Li
Position: Deputy General Manager
Tel: +86-519-83632311
Fax: +86-519-83631033
Email:lyh@hualiandressing.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Antibacterial Bandage
Common Name: Wound dressing

Regulatory Information

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

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

Device Description
The device, Antibacterial bandage, is to be applied topically to the skin for management of minor cuts, minor scrapes and minor burns. The proposed devices are available in fabric backing and plastic backing. All of devices consist of (1) backing (fabric or plastic), (2) absorbent pad (composed of Polyester fiber, viscose fiber, PE mesh, Benzalkonium chloride) and (3) release paper (composed of cellulose pulp, water, kaolin, starch, ethanol and ethylene copolymer). Each device type is available in several models. The difference between each model is the device size. This dressing contains 0.08% benzalkonium chloride which has shown effectiveness against (Staphylococcus Aureus, Pseudomonas Aeruginosa, Escherlchia coli, Enterococcus Faecalis, Klebsiella Pneumoniae, Streptococcus Pyogenes, Candida Albicans and Aspergillus Nige**r**) for up to 24 hours, as demonstrated via in vitro testing.

5. Identification of Predicate Device

510(k) Number: K113583
Product Name: Curad Antibacterial bandage

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications and is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

The proposed device was tested for the peel adhesion per ASTM D3330/D3330M. The test results show that the peel strength of the product is greater than 1.0 N/cm.

The proposed device was tested for the antimicrobial efficacy study and minimum effective concentration (MEC) study per ASTM AATCC-100, the test results meet the requirement of 4 log reduction.

Sterile barrier packaging testing were performed on the proposed device, which include seal strength (ASTM F88/F88-15). The test result showed that the device package can maintain its integrity.

Sterilization and shelf life testing listed in following table were performed on the proposed device. EO ECH residue did not exceed the limit of ISO 10993-7. Endotoxin limit did not exceed 20EU/device. Shelf life test result showed that the device can maintain its performance during the claimed shelf life.

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP 42-NF 37 <85>
Shelf Life Evaluation	Peel Adhesion, Package Tests were performed on aging samples to verify the claimed shelf life of the device

Biocompatibility testing

The contact level of the proposed device is breached or compromised surfaces, and the contact duration is limited contact (<24 hours). The proposed device was evaluated for the following tests. The results for the biocompatibility testing showed that the proposed device is biocompatible.

- Cytotoxicity,
- Sensitization,
- Intracutaneous reactivity,
- Systemic Toxicity,
- Material-mediated Pyrogenicity

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Device K201324	Predicate Device K113583	Remark
Product Code	FRO	FRO	Same
Regulation Number	Unclassified	Unclassified	Same
Class	Unclassified	Unclassified	Same
Indication for Use	Antibacterial bandage is 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 burns.	Similar
Configuration	Backing (fabric or plastic), Absorbent pad Release paper	Backing Wound pad	Difference
Single Use	Yes	Yes	Same
Size	Fabric(mm): 25×25, 30×30, 38×16, 38×19, 38×38, 50×40, 50×50, 55×19, 55×30, 55×40, 56×22, 56×29, 57×16, 60×19, 60×30, 60×40, 63×25, 65×19, 65×30, 65×40, 70×18, 70×50, 70×60, 72×19, 72×25, 72×30, 72×50, 76×19, 76×25, 76×38, 76×50, 76×57, 80×50, 80×60, 80×65, 82×19, 83×60, 84×25, 88×38, 90×60, 95×50, 100×60, 100×80, 100×100, 101×44, 101×50 Plastic(mm): 25×25, 30×30, 38×16, 38×19, 38×38, 50×40, 50×50, 55×19, 55×30, 55×40, 56×22, 56×29, 57×16, 60×19, 60×30, 60×40, 63×25, 65×19, 65×30, 65×40, 70×18, 70×50, 70×60, 72×19, 72×25, 72×30, 72×50, 76×19, 76×25, 76×38, 76×50, 76×57, 80×50, 80×60,	3/4"×3"	Difference

	80×65, 82×19, 83×60, 84×25, 88×38, 90×60, 95×50, 100×60, 100×80, 100×100, 101×44, 101×50, 101×76		
Antimicrobial	0.08-0.14% Benzalkonium chloride	0.1% Benzalkonium chloride	Similar
Material	Benzalkonium chloride Non-woven fabric Polyethylene omentum Hot melt adhesive Acrylic adhesive	Benzalkonium chloride	Similar
Biocompatibility	Complies with ISO 10993-1 for limited contact duration on breached/compromised skin	Comply with ISO 10993	Same
Sterilization	EtO Sterilization	EtO Sterilization	Same
SAL	10^{-6}	10^{-6}	Same

9. Summary of Technological Characteristics

The Antibacterial Bandage is compared to the predicate device with respect to indications for use, size, materials, antimicrobial agent, BZK concentration, etc. According to the comparison information, most of the characteristics of the subject device are the same as the predicate device, some of the characteristics are similar, one is different, but none of them will cause different safety or effectiveness issues.

Similar-Indication for Use

The indication for use of proposed bandage and predicate bandage are very similar. The slight difference between them is expression form of indication for use, however, both of the two devices can be applied topically to the skin for management of minor cuts, minor scrapes and minor burns. In addition, the antibacterial effect study was conducted on the proposed device, and the test results meet the requirement of 4 log reduction. Therefore, this difference does not affect the safety and effectiveness of the device.

Difference- Configuration

The configuration of proposed bandage and the predicate bandage are not exactly the same. However, the proposed device and predicate device are bandages that can be adhered to the patient's skin and both of them are indicated for management of minor cuts, minor scrapes and minor burns. Therefore, this difference does not affect the safety and effectiveness of the device.

Difference– Size

The size of proposed bandage and predicate bandage is different. The size will not affect the device performance of the bandage. User can select appropriate size physical requirement. Therefore, this difference is considered not to affect the safety and effectiveness of the proposed device.

Similar- Antimicrobial (BZK concentration)

The BZK concentration of proposed bandage and predicate bandage are very similar. The BZK concentration of proposed bandage is more than 0.08%, and the BZK concentration of predicate bandage is 0.1%. Although there was a small difference in BZK concentration, antibacterial effect study was conducted on the sample with minimum BZK concentration and the test results meet the requirement of 4 log reduction. Therefore, this difference does not affect the safety and effectiveness of the device.

Similar - Material

The patient contact material of proposed bandage and predicate bandage are different. However, the biocompatibility test for proposed device has been conducted and the proposed device passed all the tests. Therefore, this difference is not considered to affect the safety and effectiveness of the device.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison of the indications for use and device technological characteristics to the predicate above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.