May 31, 2024

Jinhua Jingdi Medical Supplies Co., Ltd.
℅ Julie Chen
Consultant
Shanghai Puang Technology Consulting Co., Ltd.
Building 5, No. 525 Yuanjiang Road, Minhang District
Shanghai, 201109
China

Re: K232333
Trade/Device Name: Anti-bacterial bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 3, 2024
Received: April 22, 2024

Dear Julie Chen:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232333

Device Name
Anti-bacterial bandage

Indications for Use *(Describe)*
Anti-bacterial bandages are to be applied topically to the skin for the management of minor cuts, minor scrapes.

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."

510(K) Summary

K232333

This 510(K) Summary information is being submitted in accordance with 21 CFR 807.92

I. SUBMITTER [21 CFR 807.92(a)(l)]

Company Name: Jinhua Jingdi Medical Supplies Co., Ltd.
Company Address: Building,2ditian Function,Xiaoshun Town Jingdong Zone, Jinhua, 321000 Zhejiang, P.R. China
Contact Person: Xiaojiang Hu
Position: Quality Manager
Phone Number: 0579-89116761
Email: hxj@jingdimed.com

Submission Correspondent: Julie Chen
Email: cl.julie702@gmail.com
Phone Number: +86 139 1804 5781

Summary prepared: July 31st, 2023

II. SUBJECT DEVICE [807.92(a)(2)]

Name of Device: Anti-bacterial bandage
Device Type: PE Type and Elastic Cloth Type
Classification Name: Dressing, Wound, Drug
FDA Panel: General and Plastic Surgery
Product Code: FRO
Device Class: Unclassified

III. IDENTIFICATION of PREDICATE DEVICE [807.92(a)(3)]

Company Name: Medline Industries, Inc.
Device Trade Name: CuradAntibacterial Bandage
5 IO(k) Number: Kl 13583
Classification Name: Dressing, Wound, Drug
FDA Panel: General and Plastic Surgery
Product Code: FRO
Device Class: Unclassified

IV. DEVICE DESCRIPTION [807.92(a)(4)]

The Anti-bacterial bandage is EO sterilized and is for single use only. The bandage is made of three layers: Elastic Cloth (Fabric) type (Polyethylene terephthalate) or plastic type (Polyethylene), regenerated cellulose absorbent pad, and release liner (Glassine Release Paper). The absorbent pad contains 0.8% Benzalkonium chloride. Center non-woven absorbent pad is to absorb liquid, Benzalkonium chloride present in the pad is to reduce bacterial colonization within the dressing and backing adhesive (Liquid styrene polymer with 2-methyl-1,3-butadiene, White Mineral Oil, Petroleum Resins) layer is to keep the bandage in place.

V. AVAILABEL MODELS

The proposed device is available in two types with different sizes, as shown in the below.

Type: Elastic Cloth (Fabric) type (Polyethylene terephthalate)/plastic type (Polyethylene)

Size: 25mm, 22mm, 98mm x38mm, 95mm x65mm, 90mm x20mm, 89mm x27mm, 85mm x55mm, 76mm x51mm, 76mm x45mm, 76mm x38mm, 76mm x25mm, 76mm x19mm, 75mm x50mm, 75mm x25mm, 75mm x22mm, 74mm x25mm, 74mm x24mm, 74mm x19mm, 72mm x38mm, 72mm x30mm, 72mm x25mm, 72mm x24mm, 72mm x22mm, 72mmx20mm, 72mm x19mm, 70mm x22mm, 70mm x18mm, 70mm x17mm, 6mm x75mm, 65mm x40mm, 65mm x25mm, 65mm x20mm, 56mm x19mm, 55mm x25mm, 52mm x52mm, 50mm x60mm, 50mm x50mm, 50mm x45mm, 49mm x10mm, 48mm x10mm, 46mm x10mm, 45mm x45mm, 45mm x10mm, 40mm x20mm, 40mm x10mm, 38mm x38mm, 100mm x50mm, 100mm x12.5mm, 100mm x6mm

VI. INTENDED USE [Form FDA3881]

Anti-bacterial bandages are to be applied topically to the skin for the management of minor cuts, minor scrapes.

VII. Indications for Use [21 CFR 807.92(a)(5)]

Anti-bacterial bandages are to be applied topically to the skin for the management of minor cuts, minor scrapes.

VIII. Contraindications [21 CFR 807.92(a)(5)]

The dressing should not be used on patients who are allergic to benzalkonium chloride.

IX. Substantial Equivalence [21 CFR 807.92(b)(l) and 807.92(b)(2)]

The Anti-bacterial bandage is compared with the predicate device, Curad Antibacterial Bandage (Kl13583), manufactured by Medline Industries, Inc. The results are shown below in the Technological Characteristics Comparison Table:

Table 1 Technological Characteristics Comparison Table Between Subject Device and Predicate Device

Device Item	**Proposed Device: (K232333) Anti-bacterial bandage**	**Predicate Device(K113583) Curad Antibacterial Bandage**	**SE Discussion**
Device Classification Name	Dressing, Wound, Drug	Dressing, Wound, Drug	Same
Device Class	Unclassified	Unclassified	Same
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	Same
Product Code	**FRO**	**FRO**	Same
Intended Use	Anti-bacterial bandages are to be applied topically to the skin for the management of minor cuts, minor scrapes.	Antibacterial bandages are to be applied topically to the skin to help prevent infection in minor cuts, scrapes and bums	Same
Indications for Use	Anti-bacterial bandages are to be applied topically to the skin for the management of minor cuts, minor scrapes.	Anti-bacterial bandages are to be applied topically to the skin for the management of minor cuts, minor scrapes.	Same
Mechanism of Action	Center non-woven pad for absorbing liquid, Benzalkonium chloride present in the pad for reducing bacterial colonization within dressing, Backing adhesive layer for self-adhesive and keep the bandage in place.	Center non-woven pad for absorbing liquid, Benzalkonium chloride present in the pad for reducing bacterial colonization within dressing, Backing adhesive layer for self-adhesive and keep the bandage in place.	Same
Antimicrobial agent	0.8% (w/w) benzalkonium chloride	0.8% (w/w) benzalkonium chloride	Same
Components	**(1)** Adhesive backing	**(1)** Adhesive backing	Similar

	layer (fabric or plastic); (2) Antibacterial nonstick absorbent pad layer (3) Release liner;	layer (2) Antibacterial nonstick absorbent pad layer (3) Release liner;	
Antibacterial Effectiveness	≥4 Log reduction	≥4 Log	Same
Anatomical Location	For use on minor cuts, minor scrapes.	For use on minor cuts, minor scrapes.	Same
Use time	No more than 24 hours	No more than one week	Different
Sterilization Method	Ethylene oxide sterilization	Ethylene oxide sterilization	Same
Sterilization	Ethylene Oxide Sterilization SAL:10^{-6}	Ethylene Oxide Sterilization SAL:10^{-6}	Same
Single Use	Yes	Yes	Same
Biocompatibility	Complies with ISO 10993-1 for limited contact duration on breached/compromised skin	Complies with ISO 10993-1 for limited contact duration on breached/compromised skin	Same

X. SUBSTANTIAL EQUIVALENCE DISCUSSION per 21 CFR 807.92(b)

Anti-bacterial bandage has been conducted biocompatibility studies in accordance with ISO 10993 to demonstrate the device is as safe as its predicate device. The performance bench testing was conducted to demonstrate that the subject device is as effective as its predicate device.

XI. PERFORMANCE DATA

Non-clinical Performance Test Conclusion

Biocompatibility

Based on Table A.1 of ISO 10993-1 and Table A.1 of FDA Guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1_Evaluation and testing within a risk management process", the subject device is categorized as a surface device in contact with breached or compromised surface with limited duration (<24 hours). The subject device was evaluated for:

Cytotoxicity
Sensitization
Irritation
Acute systemic toxicity
Material-mediated pyrogenicity

Bacterial Endotoxins: USP-NF <85>

Performance Bench Tests

Performance testing were conducted to verify that the proposed device met all design specifications were Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the Anti-bacterial bandage complies with the following standards:
Liquid absorbency: EN 13726-1-2002
Peel adhesion: ASTMD 3330/D3330M
Antimicrobial Efficacy: AATCC 100-2019
Minimum Bacteriostatic Concentration Test: AATCC 100-2019

Animal Study

No animal study is included in this submission.

Clinical Test Conclusion

No clinical study is included in this submission.

XII. CONCLISION per 21 CFR 807.92(c)

The conclusions drawn from the nonclinical tests demonstrate that the proposed device, the Anti-bacterial bandage is as safe, as effective, and performs as well as the legally marketed predicate device Curad Antibacterial Bandage (Kl 13583).