U.S. FOOD & DRUG ADMINISTRATION

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October 19, 2020

Planet (Suzhou) Medical Products Co., Ltd
% Van Lee
Senior Consultant
LinkHope medical technology Inc
No. 231 science avenue Huangpu district, Guangzhou
Guangzhou, GuangDong 510700
China

Re: K200821
Trade/Device Name: Anti-bacterial bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 23, 2020
Received: March 30, 2020

Dear Van Lee:

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,

For Kimberly Ferlin, Ph.D.
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200821

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.

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*"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

**1. Submission Sponsor**

Planet (Suzhou) Medical Products Co., Ltd

No.33 Qinglian Rd Xuguan Industrial Park, Hi-tech Development Zone,

Suzhou, Jiangsu,

China 215151

Contact: Frank Zhou

Contact title: General Manager

**2. Submission Correspondent**

LinkHope medical technology Inc.

No. 231 science avenue Huangpu district, Guangzhou, China

Phone: 86 -13632273583

Contact: Van Lee

Title: Senior Consultant, RA

**3. Date Prepared**

Mar 23, 2020

**4. Device Identification**

Trade/Proprietary Name: Anti-bacterial Bandage

Common/Usual Name: Wound Dressing

Classification Name: unclassified

Regulation Number: NA

Product Code: FRO

## 5. Legally Marketed Predicate Device(s)

| Device Name | 510(k) No. | Product Code | Classification Regulation | Manufacture |
|---|---|---|---|---|
| **Curad Antibacterial Bandage** | **K113583** | **FRO** | **Unclassified** | **Medline Industries, Inc.** |

## 6. Indication for Use Statement

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

## 7. Device Description

7.1.1 Anti-bacterial bandages are to be applied topically to the skin for the management of minor cuts,minor scrapes. Anti-bacterial bandage is made of Fabric tape/polyethylene tape, and absorbent pad. Absorbent pad contains 0.1%/0.8% benzalkonium chloride.

7.1.2 The Anti-bacterial bandage is EO sterilized, and is for single use only.

7.1.3 Product shelf- life time: Three years

## 8. Comparison of Technological Characteristics with predicate device

| **Manufacturer** | Planet (Suzhou) Medical Products Co., Ltd | Medline Industries, Inc. | Comparison |
|---|---|---|---|
| **Trade Name** | Anti-bacterial Bandage | Curad Antibacterial Bandage | NA |
| **510(k) Number** | K200821 | K113583 | NA |
| **Product Code** | FRO | FRO | Same |
| **Regulation Number** | NA | NA | Same |
| **Device Classif-ication Name** | dressing, wound, drug | dressing, wound, drug | Same |
| **Indications for Use** | Anti-bacterial bandages are to be applied topically to the skin for the | Antibacterial bandages are to be applied topically to the skin to help prevent infection in | Similar |

| | | | |
|---|---|---|---|
| | management of minor cuts,minor scrapes. | minor cuts, scrapes and burns. | |
| **Model** | 0.1% benzalkonium chloride, fabric tape；<br>0.8% benzalkonium chloride, fabric tape；<br>0.1% benzalkonium chloride,polyethylene tape；<br>0.8% benzalkonium chloride,polyethylene tape | 0.8% benzalkonium chloride, fabric tape；<br>0.8% benzalkonium chloride,polyethylene tape | Similar |
| **Antimicrobial agent** | Benzalkonium chloride 0.1% and 0.8% | Benzalkonium chloride 0.8% | Similar |
| **Mechanism of Action** | Benzalkonium chloride reduce bacterial colonization within dressing. | Benzalkonium chloride in the wound pad helps prevent infection. Helps prevent infection and protects cuts, scrapes or minor burns from dirt and germs | Similar |
| **Use time** | No more than 24 hours | No more than one week | Different |
| **Anatomical Location** | For use on minor cuts, minor scrapes. | For use on minor cuts, scrapes, and burns. | Similar |
| **Material** | Anti-bacterial bandage is made of Fabric tape/polyethylene tape, and absorbent pad. Absorbent pad contains 0.1%/0.8% benzalkonium chloride. | Anti-bacterial bandage is made of Fabric/polyethylene tape, and absorbent pad. Absorbent pad contains 0.8% benzalkonium chloride. | Similar |
| | | | |

| | | | |
|---|---|---|---|
| **Sterile methods** | EO sterile, compliance with ISO 11135:2014 | EO sterile, compliance with ISO 11135:2014 | Same |
| **Single-Use** | Yes | Yes | Same |
| **Shelf Life** | 3 years | 3 years | Same |
| **Complies with ISO 10993** | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-10<br>ISO 10993-11 | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-10<br>ISO 10993-11 | Same |
| **Packaging** | medical packing paper | medical packing paper | Same |

**9. Substantial Equivalence Discussion**

The Anti-bacterial Bandage is compared to the predicate device with respect to indications for use, mechanism of action, materials,antimicrobial agent, 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 new safety or effectiveness issues.

**10. Non-Clinical Performance Data**

As part of demonstrating safety and effectiveness of Anti-bacterial Bandage and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Planet (Suzhou) Medical Products Co., Ltd completed a number of non-clinical performance tests. The Anti-bacterial Bandage meets all the requirements for overall design, sterilization, biocompatibility, and other test results confirming that the design output meets the design inputs and specifications for the device.

The Anti-bacterial Bandage passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility;
  - Cytotoxicity
  - Intracutaneous reactivity
  - Acute system toxicity
  - Sensitization testing
  - Material mediated pyrogenicity
  - endotoxin testing

- Sterilization Testing
  ISO 11135:2014, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.
- Shelf Life Testing
  ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device
- Storage and Transport Testing
  ASTM 4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems
- AATCC 100：2012, Antibacterial Finishes on Textile Materials

**11. Conclusion**

Based on the above non-clinical tests and the information compared with the predicate device, the anti-bacterial bandage is as safe and as effective as the predicate device.