January 30, 2023

Winner Medical Co., Ltd.
Yi Fu
Regulatory Affairs Specialist
660 Bulong Road, Longhua District
Shenzhen,
China

Re: K221532
Trade/Device Name: PHMB Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 14, 2023
Received: January 17, 2023

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,

Julie A. Morabito -S

Julie 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)*
K221532

Device Name
PHMB Wound Dressing

Indications for Use *(Describe)*
Prescription Use:
PHMB Wound Dressings are indicated for use in the management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, first and superficial second degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

OTC Use:
For Over-the-Counter Use, PHMB Wound Dressing is used for minor abrasions, minor lacerations, minor cuts, minor scalds, 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: K221532

1. **Date of Submission**: January 26th, 2023

2. **Submitter Identification**

Winner Medical Co., Ltd.

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

Contact Person: Yi Fu

Position: Regulatory Affairs Specialist
Tel: +86-755 28138888
Fax: +86-755 28134588
Email: 3911@winnermedical.com

3. **Identification of Proposed Device**

Trade/Proprietary Name: PHMB Wound Dressing
Common name: Antibacterial Wound Dressing

Regulatory Information

Classification Name: Dressing, Wound, Drug

Classification: Unclassified

Product Code: FRO

Review Panel: General & Plastic Surgery;

4. **Identification of Predicate Device**

Primary Predicate Device: K192463

Product Name: PHMB Foam Dressing Non-Adhesive,

PHMB Foam Dressing Adhesive

Silicone PHMB Foam Dressing

Silicone PHMB Foam Dressing with Border

Manufacturer: Winner Medical Co., Ltd.

Secondary Predicate Device: K121522

Product Name: Poly FIT^{TM}+ Absorbing Antimicrobial Dressings (OTC)

Poly FIT^{TM}+ High Absorbing Antimicrobial Dressings (OTC)

Manufacturer: PolyRemedy, Inc.

5. Device Description

The proposed device PHMB Wound Dressing is a sterile wound dressing. It is used as a primary or secondary dressing to absorb wound exudates. Based on *in vitro* testing, the antibacterial agent PHMB in dressing helps to resist bacterial colonization within the dressing for up to 7 days.

The proposed device is available in two configurations,

The first one, PHMB Island Wound Dressing with acrylic adhesive, consists of a polyester viscose non-woven backing layer coated with acrylic adhesive as the top layer, a center soft absorbent pad which is made of non-woven fabric containing 0.2 % PHMB and it is laminated with the PET film, and a release liner covers on the top adhesive layer border part.

The second one, PHMB Pad Wound Dressing, only consists of a soft absorbent pad containing 0.2 % PHMB and the non-woven absorbent pad is laminated with the PET film.

The PHMB Island Wound Dressings with acrylic adhesive are supplied in a range of sizes within the range from 25 cm^2 to 400 cm^2, while for PHMB Pad Wound Dressings are supplied in a range of sizes within the range from 25 cm^2 to 225 cm^2. For each configuration, it has exactly the same materials, chemicals, and physical properties and are different only in size.

All variants of proposed device, PHMB Wound Dressing, are sterilized by Ethylene Oxide using conditions validated following ISO 11135:2014.

6. Intended Use Statement

Prescription Use:

PHMB Wound Dressings are indicated for use in the management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, first and superficial second degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

OTC Use:

For Over-the-Counter Use, PHMB Wound Dressing is used for minor abrasions, minor lacerations, minor cuts, minor scalds, and minor burns.

7. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications and 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 10993-6:2016 Biological Evaluation of Medical Devices- Part 6: Tests for Local Effects after implantation.
- 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.
- 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-NF:2021 <85> Bacterial Endotoxins Test

PHMB Wound Dressing *in vitro* testing has demonstrated ≥ 4 log-reduction of four gram positive bacteria (Vancomycin-resistant enterococcus (VRE), Bacillus subtilis, Staphylococcus aureus and Methicillin-resistant Staphylococcus aureus (MRSA)), four gram negative bacteria (Serratia marcescens, Pseudomonas aeruginosa, Escherichia coli, and Klebsiella pneumonia) challenge organisms within the dressing for up to 7 days. This testing was performed using a modified AATCC 100 method.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

The subject devices are compared with the following Predicate Devices in terms of intended use, mechanism, material, specifications, and performance. These data came from commercially product labeling and 510(k) summary.

Note: There are four available configurations in PHMB Foam Dressing (K192463). For SE comparison, the configuration—PHMB Foam Dressing Adhesive is mainly used in SE comparison, particularly in material components, technology, principle of operation, sizes and performance characteristics. This configuration, PHMB Foam Dressing Adhesive, of the primary predicate device is chosen because the dressing structure of proposed device (PHMB Island Wound Dressing) is most similar to PHMB Foam Dressing Adhesive configuration. PHMB Pad Wound Dressing is exactly the same as the absorbent pad contained in the PHMB Island Wound Dressing with acrylic adhesive.

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

Item	Subject Device K221532	Primary Predicate Device K192463	Secondary Predicate Device K121522
Product Code	FRO	FRO	FRO
Class	Unclassified	Unclassified	Unclassified
Intended Use	**Prescription Use:** PHMB Wound Dressings are indicated for use in the management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, first and superficial second degree burns,	**Prescription Use:** PHMB Foam Dressing are indicated for use in the management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds	**Prescription Use:** Under the supervision of a healthcare professional, PolyFIT™ + Absorbing Antimicrobial Dressings and PolyFIT™ + High Absorbing Antimicrobial Dressings may be used for the management of:PolyFIT™ + Absorbing Antimicrobial Dressings are intended as

	dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds. **Over-the-Counter Use:** For Over-the-Counter Use, PHMB Wound Dressing is used for minor abrasions, minor lacerations, minor cuts, minor scalds, and minor burns.	inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.	effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT™ + Absorbing Antimicrobial Dressings are for use as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3rd degree burns or for dry wounds. **Over-the-Counter Use:** For Over-the-Counter Use, PolyFIT™+ Absorbing Antimicrobial Dressings and PolyFIT™+ High Absorbing Antimicrobial Dressings may be used for minor abrasions, minor lacerations, minor cuts, minor scalds, and minor burns.
Material components	Polyester viscose non-woven fabrics layer with acrylic adhesive;	For PHMB Foam Dressing Adhesive, the dressing contains: Polyurethane top layer	Fibers containing polyethylene oxide (PEO), polyethylene-co-vinly-alcohol (EVOH),

	100% cotton absorbent pad; PHMB; PET film; Release liner.	with acrylic adhesive; Thin non-woven fabrics layer; Polyurethane foam absorbent pad; PHMB; Release liner.	polycaprolactone (PCL) and PHMB.
Technology	Absorbent pad is made of cotton which is impregnated with 0.2% (w/w) PHMB	Absorbent pad is made of a thin non-woven and polyurethane foam impregnated with 0.5% (w/w) PHMB	Dressing is made of gelling fibers which is embedded with 0.3% PHMB
Characteristics	• Absorbent pad laminated with PET film absorbs exudates • PHMB resists bacterial colonization within the dressing • Island model has adhesive border for self-adhesive	• Absorbent foam pad absorbs exudates • PHMB resists bacterial colonization within the dressing • Island model has adhesive border for self-adhesive	• Fibers absorbs exudates • PHMB inhibits microbial proliferation within the dressing and reduce microbial penetration through the dressing.
Principle of operation	Absorbent pad for absorbing liquid; PHMB presents in the center absorbent pad to resist bacterial colonization within the dressing;	Polyurethane foam pad for absorbing liquid; PHMB presents in the center absorbent foam pad to resist bacterial colonization within the dressing;	Fiber for absorbing liquid; PHMB embedded in the fibers ensures that when bacteria come in contact with PHMB molecule the outer cell wall of the bacteria is disrupted.
Model	Island Model and Pad Model	Island Model and Pad Model	NA
Antibacterial Effectiveness	⩾4 Log reduction	⩾4 Log reduction	Not publicly available
Antibacterial Duration	7 days	7 days	Not publicly available
Single use	Yes	Yes	Yes
Sterilization	EtO Sterilization	PHMB Foam Dressing Adhesive sterilized by Gamma irradiation	Not publicly available
Bio-compatibility	Biocompatibility in accordance to 10993-1	Biocompatibility in accordance to 10993-1	Biocompatibility in accordance to 10993-1

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the subject devices are determined to be Substantially Equivalent (SE) to the predicate devices.