May 14, 2020

Winner Medical Co., Ltd.
Dan Wang
Regulatory Affairs Specialist
Winner Industrial Park, No. 660 Bulong Road, Longhua District
Shenzhen, 518109CN

Re: K192463
Trade/Device Name: PHMB Foam Dressing Non-Adhesive, PHMB Foam Dressing Adhesive, Silicone PHMB Foam Dressing, Silicone PHMB Foam Dressing with Border
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 10, 2020
Received: April 14, 2020

Dear Dan Wang:

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,

Anjana Jain, 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)*
K192463

Device Name
PHMB Foam Dressing Non-Adhesive; PHMB Foam Dressing Adhesive; Silicone PHMB Foam Dressing; Silicone PHMB Foam Dressing with Border.

Indications for Use *(Describe)*
The proposed devices 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 inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

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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K192463 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: K192463

1. **Date of Submission**: 09/04/2019

2. Submitter Identification

Winner Medical Co., Ltd.

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

Contact Person: Dan Wang

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3. Identification of Proposed Device

Trade/Proprietary Name: PHMB Foam Dressing Non-Adhesive
PHMB Foam Dressing Adhesive
Silicone PHMB Foam Dressing
Silicone PHMB Foam Dressing with Border
Common name: Antimicrobial Dressing

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: K181197

Product Name: PHMB Foam Wound Dressing

5. Device Description

The subject devices are sterile, single-use dressings, the polyurethane foam contain about 0.5% (w/w) Polyhexamethylene Biguanide (PHMB), an agent that is intended to resist bacterial colonization within the dressing. The foam in the dressings has a microporous hydrophilic foam structure that absorbs wound exudate and maintains a moist wound healing environment.

Based on in vitro performance data, the PHMB Foam Wound Dressings have demonstrated to be effective against colonization and proliferation of bacteria within the dressing for up to 7 days.

The proposed device in this submission consists of four variants:

The basic one, PHMB Foam Dressing Non-adhesive, consist of a film backing laminated of acrylic adhesive (Vapor permeable and waterproof polyurethane film); a soft, absorbing polyurethane (PU) antimicrobial foam contain PHMB adhered to the top film with acrylic adhesive. The film backing has the same size with the polyurethane foam layer. The product line is available in different sizes.

A second adhesive variant, PHMB Foam Dressing Adhesive, consists of a top layer (Vapor permeable and waterproof polyurethane film); a center layer (A thin non-woven and absorbent polyurethane antibacterial foam pad containing PHMB adhered to the top film, and the top film remained with a border); a release liner (covered on the foam pad and top film border part). The product line is available in different sizes.

A third adhesive variant, Silicone PHMB Foam Dressing, consists of a top layer (Vapor permeable and waterproof polyurethane film); a center layer (Absorbent polyurethane antibacterial foam pad containing PHMB adhered to the top film); a wound contact layer (Perforated silicone gel adhered to the center layer); a release liner covers on the silicone gel. The product line is available in different sizes.

A forth adhesive variant, Silicone PHMB Foam Dressing with Border, consists of a top layer (Vapor permeable and waterproof polyurethane film); a center layer (A supper absorbent fiber pad, a thin non-woven and absorbent polyurethane antibacterial foam pad containing PHMB adhered to the top film, and the top film remained with a border); a wound contact layer (Perforated silicone gel adhered to the center layer); a release liner (covered on the silicone gel).

Silicone PHMB Foam Dressing and Silicone PHMB Foam Dressing with Border are sterilized by EtO using conditions validated following ISO 11135: 2014.
PHMB Foam Dressing Non-adhesive and PHMB Foam Dressing Adhesive are sterilized by irradiation using conditions validated following ISO 11137-2: 2013.

6. Intended Use Statement

The proposed devices 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 inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications 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 10993-7:2008 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 <85> Bacterial Endotoxins Test

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

The proposed devices are compared with the following Predicate Device in terms of intended use, mechanism, material, specifications, and performance.

K181197, PHMB Foam Wound Dressing, Manufactured by Advanced Medical Solutions Ltd.

The following table shows similarities and differences of use, design, material, and processing between the subject device and the predicate device.

These data came from commercially product labeling and 510(k) summary.

Table 1 Comparison of intended use and Technological Characteristics

Item	Proposed Devices	Predicate Device (K181197)	Substantial Equivalence
Product Code	FRO	FRO	SE
Class	Unclassified	Unclassified	SE
Intended Use	The proposed devices 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 inflicted by trauma and, as a secondary	PHMB Foam Wound Dressings 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 inflicted by trauma	SE

	cover dressing for packed wounds.	and, as a secondary dressing or cover dressing for packed wounds.	
Mechanism	Polyurethane foam and super absorbent fiber pad for absorbing liquid; PHMB present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for vapor permeable and waterproof.	Polyurethane foam for absorbing liquid; PHMB present in the foam for reducing bacteria colonization in the dressing; Clear polyurethane wound contact layer with acrylic adhesive for self-adhesive; Backing film for vapor permeable and waterproof.	SE
Material	Polyurethane film, polyurethane foam contain PHMB, release liner, some with super absorbent fiber, non - woven fabrics or	Polyurethane film, Polyurethane foam containing PHMB, Clear polyurethane with acrylic adhesive	No new questions of safety or effectiveness raised.
Antimicrobial Effectiveness	Reduction of Staphylococcus aureus, Escherlchia coli, Candida albicans, Pseudomona aeruginosa, MRSA, VRE, Klebsiella	Reduction of MRSA , MRSE, VRE, Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumonia, Candida albicans, Rhodotorula mucilaginosa > 4 log	SE
Antibacterial Duration	7days	7days	SE
Single Use	Yes	Yes	SE
Sterilization	PHMB Foam Dressing Non- Adhesive, PHMB Foam Dressing Adhesive sterilized by irradiation; Silicone PHMB Foam Dressing, Silicone PHMB Foam Dressing with Border	Irradiation	
Biocompatibility	Biocompatibility in accordance to 10993-1(breached or compromised surfaces with prolonged	Biocompatibility in accordance to 10993-1(breached or compromised surfaces with	

		prolonged contact(>24h to 30d))	

The proposed device has the same intended use, and similar technological characteristics to the predicate device. In order to address the questions raised from differences in technological characteristics, biocompatibility tests according to 10993-1 and antimicrobial effectiveness tests according to modified AATCC 100 were conducted. These are no new questions of the safety and efficacy raised.

10. Substantially Equivalent (SE) Conclusion

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