January 17, 2023

Winner Medical Co., Ltd.
Mingni Liu
Regulatory Affairs Specialist
Winner Industrial Park, No. 660 Bulong Road,
Loughua District
Shenzhen, Guangdong 518109
China

Re: K221754
Trade/Device Name: Ag Foam Dressing Non-Adhesive (OTC); Ag Foam Dressing Adhesive (OTC); Silicone Ag Foam Dressing (OTC); Silicone Ag Foam Dressing with Border (OTC)
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 24, 2022
Received: November 25, 2022

Dear Mingni Liu:

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 and Part 809); 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)*
K221754

Device Name
Ag Foam Dressing Non-Adhesive,Ag Foam Dressing Adhesive,Silicone Ag Foam Dressing,Silicone Ag Foam Dressing with Border

Indications for Use *(Describe)*
The Silicone Ag Foam Dressing (OTC) /Silicone Ag Foam Dressing with Border (OTC)/ Ag Foam Dressing Non-adhesive (OTC) and Ag Foam Dressing Adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, 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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Tab #7 510(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: K221754

1. **Date of Submission**: June 08, 2022

2. Submitter Identification

Winner Medical Co., Ltd.

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

Contact Person: Mingni Liu

Position: Regulatory Affairs Specialist
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3. Identification of Proposed Device

Trade/Proprietary Name: Ag Foam Dressing Non-Adhesive (OTC)
Ag Foam Dressing Adhesive (OTC)
Silicone Ag Foam Dressing (OTC)
Silicone Ag Foam Dressing with Border (OTC)

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

Primary Predicate Device:

510(k) Number: K191819

Product Name: Ag Foam Dressing Non-Adhesive
Ag Foam Dressing Adhesive
Silicone Ag Foam Dressing
Silicone Ag Foam Dressing with Border
Manufacturer: Winner Medical Co., Ltd.

Secondary Predicate Device:

510(k) Number: K180570

Product Name: Silverlon® Island Wound Dressing, Silverlon® Wound Pad Dressing (also known as Silverlon® Burn Pad Dressing)
Manufacturer: Argentum Medical, LLC

5. Device Description

It is a sterile, single-use dressing, the foam layer contain about 0.25-0.35mg/cm^2 silver. The dressing absorbs wound exudate and releases silver ions within the dressing in the presence of wound fluid to help reduce bacterial colonization of the dressing. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The devices are available in four configurations:

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

A second adhesive configuration, Ag 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 silver compounds adhered to the top film, and the top film remained border part); a release liner (covered on the foam pad and top film border part). The product line is available in different sizes.

A third adhesive configuration, Silicone Ag Foam Dressing, consists of a top layer (Vapor permeable and waterproof polyurethane film); a center layer (Absorbent polyurethane antibacterial foam pad containing silver compounds adhered to the top film); a wound contact

layer (Perforated laminate of acrylic adhesive/polyurethane film/silicone gel, where the acrylic adhesive adheres to the top film, and the silicone gel is for skin adherence); a release liner covers on the silicone gel. The product line is available in different sizes.

A forth adhesive configuration, Silicone Ag 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 silver compounds adhered to the top film, and the top film remained border part); a wound contact layer (Perforated silicone gel adhered to the center layer and top film); a release liner (covered on the silicone gel).

The dressing has light yellow or light brown appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings can absorb exudates, maintains a moist wound healing environment and has good antibacterial properties. It has been shown that antibacterial effectiveness within the dressing for up to 7 days, as demonstrated in vitro.

Silicone Ag Foam Dressing and Silicone Ag Foam Dressing with Border are sterilized and sold directly to users after sterilized by EtO using conditions validated following ISO 11135-1: 2014. Ag Foam Dressing Non-adhesive and Ag Foam Dressing Adhesive are sterilized and sold directly to users after sterilized by irradiation using conditions validated following ISO 11137-2: 2013.

The Silicone Ag Foam Dressing (OTC) /Silicone Ag Foam Dressing with Border (OTC)/ Ag Foam Dressing Non-adhesive (OTC) and Ag Foam Dressing Adhesive (OTC) are substantially equivalent in composition, material components, function and performance to Winner's Silicone Ag Foam Dressing (Rx) /Silicone Ag Foam Dressing with Border (Rx)/ Ag Foam Dressing Non-adhesive (Rx) /Ag Foam Dressing Adhesive (Rx) cleared by FDA under 510(k) K191819. The primary purpose of this 510(k) is to allow OTC retail marketing of this dressing. Labeling of the OTC product has been revised to include added directions for use for a non-professional retail population.

6. Indications for use

The Silicone Ag Foam Dressing (OTC) /Silicone Ag Foam Dressing with Border (OTC)/ Ag Foam Dressing Non-adhesive (OTC) and Ag Foam Dressing Adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.

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. Since the proposed device has the same device design as the primary predicate device, the tests performed for the primary predicate device can be leveraged for the proposed device. These tests including: cytotoxicity, skin sensitization, irritation, acute systemic toxicity, pyrogen, implantation and subacute systemic toxicity, bacterial endotoxin, antimicrobial effectiveness test, EO ECH residue test.

The performance test, including antimicrobial effectiveness test, liquid absorbency, waterproofness and moisture vapor transmission rate were conducted on the proposed 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 <85> Bacterial Endotoxins Test

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

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

- Primary Predicate Device:
  510(k) Number: K191819
  Product Name: Ag Foam Dressing Non-Adhesive / Ag Foam Dressing Adhesive / Silicone Ag Foam Dressing / Silicone Ag Foam Dressing with Border, Manufactured by Winner Medical Co., Ltd.
- Secondary Predicate Device:
  510(k) Number: K180570
  Product Name: Silverlon® Island Wound Dressing, Silverlon® Wound Pad Dressing (also known as Silverlon® Burn Pad Dressing), Manufactured by Argentum Medical, LLC.

The following table shows similarities and differences of use, design, material, and processing methods between proposed device and two predicate devices.

Table 1 Comparison of intended use and Technological Characteristics

Item	Proposed Device	Primary Predicate Device (K191819)	Secondary Predicate Device (K180570)
Product Code	FRO	FRO	FRO
Class	Unclassified	Unclassified	Unclassified

Intended Use	The Silicone Ag Foam Dressing (OTC) /Silicone Ag Foam Dressing with Border (OTC)/ Ag Foam Dressing Non-adhesive (OTC) and Ag Foam Dressing Adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.	Ag Foam Dressings are for prescription use, which are indicated for the management of moderately to highly exuding wounds, such as leg and foot ulcers, pressure ulcers, diabetic foot ulcers, traumatic and surgical wounds, donor sites, 1st and 2nd degree burns.	The Over-The-Counter Indications: The Silverlon® Island Wound Dressing and Silverlon® Wound Pad Dressing are for local management of superficial wounds, minor burns, abrasions and lacerations.
Mechanism	Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.	Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.	Laminate pad for absorbing wound exudate; Silver coated nylon fiber wound contact layer delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive
Material	Polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner	Polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner	Nylon fiber coated with metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.
Antibacterial Duration	7 days	7 days	7 days
Single Use	Yes	Yes	Yes

Sterilization	Ag Foam Dressing Non-Adhesive (OTC) & Ag Foam Dressing Adhesive(OTC) sterilization by gamma irradiation; Silicone Ag Foam Dressing (OTC) & Silicone Ag Foam Dressing with Border (OTC) sterilization by EtO. SAL: 10^{-6}	Ag Foam Dressing Non-Adhesive & Ag Foam Dressing Adhesive sterilization by gamma irradiation; Silicone Ag Foam Dressing & Silicone Ag Foam Dressing with Border sterilization by EtO. SAL: 10^{-6}	Sterilization by: EtO. SAL: 10^{-6}
Biocompatibility	Biocompatibility in accordance to 10993-1(breached or compromised surfaces with prolonged contact(>24h to 30d))	Biocompatibility in accordance to 10993-1(breached or compromised surfaces with prolonged contact(>24h to 30d))	Biocompatibility in accordance to 10993-1(breached or compromised surfaces with prolonged contact(>24h to 30d))

The compositions, materials, function and performance of the proposed devices are substantially equivalent to the primary predicate devices. The proposed devices are for OTC use, therefore their intended use is substantially equivalent to the secondary predicate device, Silverlon® Island Wound Dressing (for OTC use)and Silverlon® Wound Pad Dressing (for OTC use), while the primary predicate device is for prescription use. All of these devices pad for absorbing wound exudate, contain silver ions to reduce bacteria colonization in the dressing, and top layer for self-adhesive. In order to address the questions raised from differences, biocompatibility tests according to 10993-1 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.