May 14, 2020

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

Re: K191819
Trade/Device Name: Ag Foam Dressing Non-Adhesive, Ag Foam Dressing Adhesive, Silicone Ag Foam Dressing, Silicone Ag Foam Dressing with Border
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 27, 2019
Received: July 5, 2019

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)*
K191819

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 proposed devices are indicated for the management of moderately to highly exuding wounds, such as leg and foot ulcers, pressure ulcers, diabetic foot ulcers, skin abrasions, surgical wounds, donor sites, 1st and 2nd degree 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.

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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: K191819

1. **Date Prepared**: 05/14/2020

2. **Submitter Identification**

Winner Medical Co., Ltd.

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3. **Identification of Proposed Device**

Trade/Proprietary Name: Ag Foam Dressing Non-Adhesive
Ag Foam Dressing Adhesive
Silicone Ag Foam Dressing
Silicone Ag 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**

Primary Predicate Device:

510(k) Number: K120828

Product Name: Biatain Silicone Ag Foam Dressings

Secondary Predicate Device:
510(k) Number: K100218
Product Name: Biatain Ag Foam Dressing

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 proposed 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.

6. Intended Use Statement

The proposed devices are indicated for the management of moderately to highly exuding wounds, such as leg and foot ulcers, pressure ulcers, diabetic foot ulcers, skin abrasions, surgical wounds, donor sites, 1st and 2nd degree 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. 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

Silver Foam Dressing is compared with the following Predicate Device in terms of intended use, mechanism, material, and performance.

K120828, Biatain Silicone Ag Foam Dressings, Manufactured by Coloplast A/S.

K100218, Biatain Ag Foam Dressings, Manufactured by Coloplast A/S.

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

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

Table 1 Comparison of intended use and Technological Characteristics

Item	Proposed Device	Primary Predicate Device (K120828)	Secondary Predicate Device (K100218)
Product Code	FRO	FRO	FRO
Class	Unclassified	Unclassified	Unclassified

Intended Use	The proposed devices 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.	Biatain Silicone Ag Foam Dressings are indicated for use in the management of moderately to highly exuding leg ulcers and pressure sores. The dressing can also be used for 2nd degree bumns, donor sites, post operative wounds and skin abrasions.	Biatain Ag Foam Adhesive & Non-Adhesive Dressings are indicated for use in the management of moderately to highly exuding leg ulcers and pressure sores. The dressing can also be used for 2nd degree burns, donor sites, post operative wounds and skin abrasions. Biatain Ag Foam Non-Adhesive Dressings are additionally indicated for diabetic foot ulcers.
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.	Same	Same
Material	Polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone, Release liner	Polyurethane film , Polyurethane foam containing silver, Silicone contact layer, Release liner	Polyurethane foam containing silver, Polyurethane film Release liner
Antibacterial Duration	7 days	7 days	7 days
Single Use	Yes	Yes	Yes
Sterilization	Ag Foam Dressing Non-Adhesive & Ag Foam Dressing Adhesive sterilization by irradiation;	Sterilization by: EtO SAL: 10^{-6}	Sterilization by: Irradiation SAL: 10^{-6}

	Silicone Ag Foam Dressing & Silicone Ag Foam Dressing with Border sterilization byEtO. 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 proposed device has 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 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.