December 21, 2022

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

Re: K221720
Trade/Device Name: Extra Silver Gelling Fiber Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 25, 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); 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)*
K221720

Device Name
Extra Silver Gelling Fiber Dressing

Indications for Use *(Describe)*
Prescription Use:
Under the supervision of a healthcare professional. Extra Silver Gelling Fiber Dressing may be used for the management of moderate to heavily exuding chronic and acute wounds as follow:
• Partial thickness (second degree) burns;
• Pressure ulcers (partial and full thickness);
• Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology);
• Diabetic foot ulcers;
• Surgical wounds that heal by primary intent such as dermatological and surgical incisions;
• Surgical wounds left to heal by secondary intention such as dehisced surgical incisions and donor sites;
• Traumatic wounds

OTC Use:
Extra Silver Gelling Fiber Dressing may be used for the management of:
• Minor Abrasions
• Minor Lacerations
• Minor cuts
• Minor scalds and 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

The assigned 510(k) Number: K221720

1. **Date of Submission**: December 14, 2022

2. Submitter Identification

Winner Medical Co., Ltd.

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3. Identification of Proposed Device

Trade/Proprietary Name: Extra Silver Gelling Fiber Dressing
Common name: Wound or Burn 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: K210466
Product Name: Silver Gelling Fiber Dressing
Manufacturer: Winner Medical Co., Ltd.
Reference Device:
510(k) Number: K121275
Product Name: AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber
Manufacturer: ConvaTec Inc.

5. Device Description

Extra Silver Gelling Fiber Dressing is a soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose (CMC) fibers, strengthening fibers and 1.2% ionic silver. This dressing absorbs wound fluid and creates a soft gel that conforms to the wound surface, maintains a moist environment. A moist wound environment supports the body's healing process. The silver antimicrobial may help reduce bacterial colonization within the dressing for up to 7 days.

The dressings are supplied sterile in a range of sizes, ranging in area from 25cm^2 to 600cm^2. All dressings have the exactly the same material, chemical, and physical properties and are different only in size.

All dressings are sterilized and sold after sterilization by gamma radiation using conditions validated following ISO 11137-2:2013.

6. Indications for use

OTC Use:

Extra Silver Gelling Fiber Dressing may be used for the management of:

• Minor Abrasions

• Minor Lacerations

• Minor cuts

• Minor scalds and burns

Prescription Use:

Under the supervision of a healthcare professional. Extra Silver Gelling Fiber Dressing may be used for the management of wounds as follow:

• Partial thickness (second degree) burns;

• Pressure ulcers (partial and full thickness);

• Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology);

• Diabetic foot ulcers;

• Surgical wounds that heal by primary intent such as dermatological and surgical incisions;

• Surgical wounds left to heal by secondary intention such as dehisced surgical incisions and donor sites;

• Traumatic wounds

The indications for use are identical to the primary predicate device (K210466).

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. 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 10993-10:2010 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

AATCC 100-2012 Antibacterial Finishes on Textile Materials: Assessment of

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Technological Characteristics Comparison

Extra Silver Gelling Fiber Dressing has the same intended use and indications for use as the predicate device but has an additional tensile strength performance than the predicate device. This is achieved by addition strengthening fibers. The differences in the composition and technology, as detailed below, is explained by the addition of strengthening fibers in the proposed device as compared to the predicate device. There are no differences in operation and directions for use between Extra Silver Gelling Fiber Dressing and the predicate device.

Table 1 Comparison of Intended use, Design and Technological Characteristics

Item	Proposed Device	Predicate Device (K210466)	Comparison

Product Code	FRO	FRO	Equivalent
Class	Unclassified	Unclassified	Equivalent
Indication for Use	**Over-the-Counter Use:** Silver Gelling Fiber Dressing may be used for the management of: • Minor abrasions • Minor lacerations • Minor cuts • Minor scalds and burns **Prescription Use:** Under the supervision of a healthcare professional: Silver Gelling Fiber Dressing may be used for the management of wounds as follow: • Partial thickness (second degree) burns; • Pressure ulcers (partial and full thickness); • Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology); • Diabetic foot ulcers; • Surgical wounds that heal by primary intent such as dermatological and surgical incisions; • Surgical wounds left to heal by secondary intention such as dehisced surgical incisions and donor sites; • Traumatic wounds	**Over-the-Counter Use:** Silver Gelling Fiber Dressing may be used for the management of: • Minor abrasions • Minor lacerations • Minor cuts • Minor scalds and burns **Prescription Use:** Under the supervision of a healthcare professional: Silver Gelling Fiber Dressing may be used for the management of wounds as follow: • Partial thickness (second degree) burns; • Pressure ulcers (partial and full thickness); • Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology); • Diabetic foot ulcers; • Surgical wounds that heal by primary intent such as dermatological and surgical incisions; • Surgical wounds left to heal by secondary intention such as dehisced surgical incisions and donor sites; • Traumatic wounds	Equivalent
Principle of operation	The dressing absorbs wound fluid and creates a soft, conformable gel, which maintains a moist wound environment to support the healing process. Silver ionic present in the fiber for reducing bacteria colonization in the dressing.	The dressing absorbs wound fluid and creates a soft, conformable gel, which maintains a moist wound environment to support the healing process. Silver ionic present in the fiber for reducing bacteria colonization in the dressing.	Equivalent

Material components	Composed of sodium carboxymethylcellulose , strengthening fibers (polyester thread) and ionic silver	Composed of sodium carboxymethylcellulose and ionic silver	Similar
Technology	Silver impregnated sodium carboxymethylcellulose fibers needling together and stitch bonded with polyester thread to non-woven pad or ribbon;	Silver impregnated sodium carboxymethylcellulose fibers needling together to non-woven pad or ribbon	Similar
Characteristics	• Sterile • Absorbs exudate (including bacteria) • Forms a soft conformable gel • The silver in the dressing kills bacteria held in the dressing • May require a secondary dressing	• Sterile • Absorbs exudate (including bacteria) • Forms a soft conformable gel • The silver in the dressing kills bacteria held in the dressing • May require a secondary dressing	Equivalent
Antibacterial Duration	7 days	7 days	Equivalent
Single Use	Yes	Yes	Equivalent
Sterilization	Gamma Radiation	Gamma Radiation	Equivalent
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))	Equivalent

The proposed device has same intended use, principle of operation and characteristics to the predicate device.

10. Non-Clinical Testing – Performance

Mechanical testing was conducted for this submission. Absorbency performance is equivalent to the predicate device; tensile strength performance is superior to the predicate device due to the addition strengthening fibers design modification.

Extra Silver Gelling Fiber 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.

11. Non-Clinical Testing – Biocompatibility

Biocompatibility testing was conducted for this submission in accordance with the US Food and Drug Administration's guidance entitled Use of International Standard ISO‑10993: 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' and test results meet the requirements.

12. Conclusions

The proposed device and the predicate device underwent evaluation that demonstrates substantial equivalence in the intended use of each device, biocompatibility, safety, efficacy, environment of use, and the principles of operation. Therefore, the proposed device demonstrates substantial equivalence to the predicate device.