January 14, 2022

Winner Medical Co., Ltd.
Haoyuan He
Regulatory Affairs Specialist
Winner Industrial Park, No. 660 Bulong Road, Longhua District
Shenzhen, Guangdong 51809
China

Re: K210466
Trade/Device Name: Silver Gelling Fiber Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 17, 2021
Received: September 27, 2021

Dear Haoyuan He:

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 Morabito, 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)*

Device Name
Silver Gelling Fiber Dressing

Indications for Use *(Describe)*

Prescription Use:

Under the supervision of a healthcare professional. 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:

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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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: K210466

1. **Date of Submission**: February 9, 2021

2. Submitter Identification

Winner Medical Co., Ltd.

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

Contact Person: Haoyuan He

Position: Regulatory Affairs Specialist
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3. Identification of Proposed Device

Trade/Proprietary Name: 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

Primary Predicate Device:

510(k) Number: K080383

Product Name: AQUACEL HYDROFIBER WOUND DRESSING AND AG HYDROFIBER DRESSING
Manufacturer: CONVATEC, A DIVISION OF E.R. SQUIBB & SONS, L.L.C

5. Device Description

Silver Gelling Fiber Dressing is a soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose 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 and aids in the removal of non-viable tissue from the wound (autolytic debridement). 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:

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

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 10993-10:2010 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

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.

A porcine wound healing study was carried out to evaluate the silver cytotoxicity of subject device. The study demonstrated that there were no biologically relevant differences between the test subjects (Silver Gelling Fiber Dressing, and a Control AQUACEL® Ag Hydrofiber Dressing) in terms of wound healing performance characteristics and local tolerance after wound creation.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Silver Gelling Fiber Dressing is compared with the following Predicate Device in terms of intended use, principle of operation, material, technology, characteristics and performance.
K080383, AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing Manufactured by ConvaTec.

The following table shows comparison between proposed device and predicate devices.
These data came from commercially product labeling and 510(k) summary.

Table 1 Comparison of Intended use, Design and Technological Characteristics

Item	Proposed Device	Predicate Device(K080383)
Product Code	FRO	FRO
Class	Unclassified	Unclassified
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;	**Over-the-Counter Use:** AQUACEL® Hydrofiber® Wound Dressing may be used for: • Abrasions • Lacerations • Minor cuts • Minor scalds and burns **Prescription Use:** Under the supervision of a healthcare professional: AQUACEL® Ag Hydrofiber Dressing may be used for the management of: •Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection; •Partial thickness (second degree) burns; •Diabetic foot ulcers, leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness); •Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;

	• Surgical wounds left to heal by secondary intention such as dehisced surgical incisions and donor sites; • Traumatic wounds	• Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular); • Traumatic wounds; •Wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided and donor sites; • Oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma; •Management of painful wounds; •Infected Wounds;
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.
Material components	Composed of sodium carboxymethylcellulose and 1.2% ionic silver	Composed of sodium carboxymethylcellulose (Hydrofiber™) and 1.2% ionic silver
Technology	Silver impregnated sodium carboxymethylcellulose fibers needled together to non-woven pad or ribbon	Silver impregnated sodium carboxymethylcellulose fibers needled together to non-woven pad or ribbon
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
Antibacterial Duration	7 days	7 days
Single Use	Yes	Yes
Sterilization	Radiation	Radiation

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))

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

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.