



December 19, 2025

Qingdao Bright Moon Biomedical Materials Co., Ltd.  
Huixin Wang  
R&D Department Manager  
No. 788, Bright Moon Road, Huangdao District  
Qingdao, Shandong 266499  
China

Re: K252167

Trade/Device Name: Enhanced Silver Gelling Fiber Dressing (OTC) Extra Enhanced Silver Gelling  
Fiber Dressing (Prescription)

Regulatory Class: Unclassified

Product Code: FRO

Dated: November 19, 2025

Received: November 19, 2025

Dear Huixin 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.

Assistant Director

DHT4B: Division of Plastic and

Reconstructive Surgery Devices

OHT4: Office of Surgical and

Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (*if known*)  
K252167

Device Name

Enhanced Silver Gelling Fiber Dressing(OTC)  
Extra Enhanced Silver Gelling Fiber Dressing

Indications for Use (*Describe*)

Enhanced silver gelling fiber dressing (OTC) may be used for the management of:

Abrasions  
Lacerations;  
Minor cuts;  
Minor scalds and burns.

Extra enhanced silver gelling fiber dressing (Rx only) may be used for the management of:

Partial thickness (superficial 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 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;

Model:

(YE05, YE10, YE15, YE20, YE25, YE30, YE40, YE50, YE60, YE65, YT13, YT02, YT03, YT04, YT05, YT06, YE22, YE11, YE19, YT09, YT15, YT16)

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 information is being submitted in accordance with 21 CFR 807.92.

### **I. SUBMITTER:**

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Summary prepared: Dec 19<sup>th</sup>, 2025

### **II. SUBJECT DEVICE**

Name of Device: Enhanced Silver Gelling Fiber Dressing (OTC)  
Extra Enhanced Silver Gelling Fiber Dressing (Prescription)  
Classification Name: Dressing, Wound, Drug  
FDA Panel: General and Plastic Surgery  
Regulatory Class: Unclassified  
Product Code: FRO

### **III. PREDICATE DEVICE**

Predicate Device: AQUACEL Ag+ EXTRA Enhanced Hydrofiber Dressing with Silver and Strengthening Fiber (K173675)  
Classification Name: Dressing, Wound, Drug  
FDA Panel: General and Plastic Surgery  
Regulatory Class: Unclassified  
Product Code: FRO

#### IV. DEVICE DESCRIPTION

Enhanced silver gelling fiber dressing (OTC)/Extra Enhanced Silver Gelling Fiber Dressing (Prescription) is a soft, conformable, sterile dressing composed of sodium carboxymethyl cellulose fibers, strengthening layer (polyester), 1.2% (w/w) ionic silver, and stitched with enhance fibers (polyester). This conformable dressing absorbs wound fluid and creates a soft gel, provides a moist wound healing environment, and release silver ions within the dressing in the presence of wound fluid to help reduce bacteria within the dressing. Based on in-vitro testing, the silver in the dressing inhibits bacterial growth in the dressing for up to seven days.

#### V. AVAILABLE MODELS

The proposed device is available in different sizes, as shown in the following table:

**Table 1 Device model of Enhanced Silver Gelling Fiber Dressing (OTC) / Extra Enhanced Silver Gelling Fiber Dressing (Prescription)**

| Device Name                                                                                              | Shape | Ref  | Specification (cm) | Tolerance |
|----------------------------------------------------------------------------------------------------------|-------|------|--------------------|-----------|
| Enhanced Silver Gelling Fiber Dressing (OTC)/Extra Enhanced Silver Gelling Fiber Dressing (Prescription) | Sheet | YE05 | 5*5                | ±5%       |
|                                                                                                          |       | YE10 | 10*10              | ±5%       |
|                                                                                                          |       | YE15 | 12.5*12.5          | ±5%       |
|                                                                                                          |       | YE20 | 10*20              | ±5%       |
|                                                                                                          |       | YE25 | 15*20              | ±5%       |
|                                                                                                          |       | YE30 | 7.5*12             | ±5%       |
|                                                                                                          |       | YE40 | 10*15              | ±5%       |
|                                                                                                          |       | YE50 | 15*15              | ±5%       |
|                                                                                                          |       | YE60 | 20*20              | ±5%       |
|                                                                                                          |       | YE65 | 15*25              | ±5%       |
|                                                                                                          |       | YT13 | 2*45               | ±5%       |

|  |  |      |           |     |
|--|--|------|-----------|-----|
|  |  | YT02 | 2*10      | ±5% |
|  |  | YT03 | 2*5       | ±5% |
|  |  | YT04 | 2*30      | ±5% |
|  |  | YT05 | 3*30      | ±5% |
|  |  | YT06 | 4*30      | ±5% |
|  |  | YE22 | 10.8*10.8 | ±5% |
|  |  | YE11 | 10*12.5   | ±5% |
|  |  | YE19 | 7.5*7.5   | ±5% |
|  |  | YT09 | 3*44      | ±5% |
|  |  | YT15 | 2*35      | ±5% |
|  |  | YT16 | 4*20      | ±5% |

**VI. INDICATIONS for USE per 21 CFR 807.92(A)(5)****Prescription Use:**

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

- Partial thickness (superficial 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 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;

**Over-the-Counter Use:****Over-the-Counter:**

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

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

**VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH  
THE PREDICATE DEVICE per 21 CFR 807.92(a)(6)**

Enhanced Silver Gelling Fiber Dressing(OTC) /Extra Enhanced Silver Gelling Fiber Dressing (Prescription) is compared with the predicate device AQUACEL Ag+ EXTRA Enhanced Hydrofiber Dressing with Silver and Strengthening Fiber (K173675), manufactured by ConvaTec Limited. The results are shown below in the Technological Characteristics Comparison Table:

**Table 2 Technological Characteristics Comparison Table Between Subject  
Device and Predicate Device**

| <b>Item</b>    | <b>Proposed Device</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Predicate Device (K173675)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Comparison</b> |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Product Code   | FRO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | FRO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Same              |
| Classification | Unclassified                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Unclassified                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Same              |
| Review Panel   | General & Plastic Surgery                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | General & Plastic Surgery                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Same              |
| Intended Use   | <p>Over-the-Counter Use:</p> <p>Enhanced silver gelling fiber dressing may be used for the management of:</p> <ul style="list-style-type: none"> <li>• Abrasions</li> <li>• Lacerations</li> <li>• Minor cuts</li> <li>• Minor scalds and burns</li> </ul> <p>Prescription Use:</p> <p>Under the supervision of a healthcare professional. Extra Enhanced Antibacterial Silver Gelling Fiber Dressing may be used for the management of wounds as follow:</p> <ul style="list-style-type: none"> <li>• Partial thickness (superficial second degree) burns;</li> <li>• Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial &amp; full thickness);</li> <li>• Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;</li> <li>• Surgical wounds that heal by</li> </ul> | <p>Over-the-Counter Use:</p> <p>AQUACEL™ Ag+ EXTRA Enhanced Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of:</p> <ul style="list-style-type: none"> <li>• Abrasions</li> <li>• Lacerations</li> <li>• Minor cuts</li> <li>• Minor scalds and burns</li> </ul> <p>Prescription Use:</p> <p>Under the supervision of a healthcare professional:</p> <p>AQUACEL™ Ag+ EXTRA Enhanced Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of:</p> | Same              |

|  |                        |  |  |
|--|------------------------|--|--|
|  | primary intent such as |  |  |
|--|------------------------|--|--|

|                |                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |      |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
|                | <p>dermatological and surgical incisions (e.g., orthopedic and vascular);</p> <ul style="list-style-type: none"> <li>• Traumatic wounds;</li> <li>• Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;</li> </ul> | <ul style="list-style-type: none"> <li>• Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;</li> <li>• Partial thickness (second degree) burns;</li> <li>• Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial &amp; full thickness);</li> <li>• Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;</li> <li>• Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular);</li> <li>• Traumatic wounds;</li> <li>• Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;</li> <li>• Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;</li> <li>• Management of painful wounds;</li> <li>• Infected wounds</li> </ul> |      |
| Single Use     | Yes                                                                                                                                                                                                                                                                                  | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Same |
| Mode of Action | The dressing absorbs wound fluid and creates a soft, conformable gel, which                                                                                                                                                                                                          | The dressing absorbs wound fluid and creates a soft, conformable gel, which                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Same |

|                        |                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                             |           |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
|                        | <p>maintains a moist wound environment to support the healing process.</p> <p>The release silver ions within the dressing in the presence of wound fluid to help reduce bacteria within the dressing.</p> <p>The silver in the dressing inhibits bacterial growth in the dressing for up to seven days.</p> | <p>maintains a moist wound environment to support the healing process.</p> <p>The release silver ions within the dressing in the presence of wound fluid to help reduce bacteria within the dressing.</p> <p>The silver in the dressing inhibits bacterial growth in the dressing for up to seven days.</p> |           |
| Components             | Sodium carboxymethylcellulose (CMC) fibers, strengthening layer, strengthening fibers and 1.2% (w/w) ionic silver                                                                                                                                                                                           | Composed of sodium carboxymethylcellulose (Hydrofiber™) and 1.2% ionic silver with EDTA and benzethonium chloride                                                                                                                                                                                           | Different |
| Antibacterial Duration | 7 days                                                                                                                                                                                                                                                                                                      | 7 days                                                                                                                                                                                                                                                                                                      | Same      |
| 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))                                                                                                                                                                                            | Same      |
| Liquid Absorbency      | 20.55g/100cm <sup>2</sup>                                                                                                                                                                                                                                                                                   | 20.26g/100cm <sup>2</sup>                                                                                                                                                                                                                                                                                   | Different |
| Sterile                | Sterile                                                                                                                                                                                                                                                                                                     | Sterile                                                                                                                                                                                                                                                                                                     | Same      |
| Sterilization          | Radiation<br>SAL:10 <sup>-6</sup>                                                                                                                                                                                                                                                                           | Radiation<br>SAL:10 <sup>-6</sup>                                                                                                                                                                                                                                                                           | Same      |

## VIII. SUBSTANTIAL EQUIVALENCE DISCUSSION per 21 CFR 807.92(b)

Enhanced Silver Gelling Fiber Dressing(OTC) /Extra Enhanced Silver Gelling Fiber Dressing (Prescription) has been conducted biocompatibility studies in accordance with ISO 10993 to demonstrate the device is as safe as its predicate device. The performance bench testing was conducted to demonstrate that the subject device is as effective as its predicate device.

## IX. PERFORMANCE DATA

### Non-Clinical Performance Test Conclusion

#### Biocompatibility

Based on Table A.1 of ISO 10993-1 and Table A.1 of FDA Guidance “Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1\_Evaluation and testing within a risk management process”, the subject device is categorized as a surface device in contact with breached or compromised surface with prolonged duration. The subject device was evaluated for:

Cytotoxicity  
Sensitization  
Irritation  
Acute systemic toxicity  
Subacute systemic toxicity  
Implantation  
Material-mediated pyrogenicity

#### Performance Bench Testing

Performance testing was 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:

Liquid absorbency EN 13726-1-2002  
Loss on Drying: USP <731>  
pH Value: USP <791>  
Antimicrobial Efficacy: AATCC 100-2019  
Minimum Antimicrobial Efficacy Test: AATCC 100-2019

**Clinical Test Conclusion**

No clinical study is included in this submission.

**X. CONCLUSION per 21 CFR 807.92(c)**

The conclusion drawn from the nonclinical tests demonstrates that the subject device, the Enhanced Silver Gelling Fiber Dressing(OTC)/Extra Enhanced Silver Gelling Fiber Dressing (Prescription) is as safe, as effective, and performs as well as the legally marketed predicate device AQUACEL Ag+ EXTRA Enhanced Hydrofiber Dressing with Silver and Strengthening Fiber (K173675).