March 16, 2023

Qingdao Bright Moon Biomedical Materials Co., Ltd.
Deng Yunlong
R&D Department Manager
No. 788, Bright Moon Road, Huangdao District
Qingdao, Shandong 266400
China

Re: K220673
Trade/Device Name: Sterile Silver Alginate Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 13, 2023
Received: February 14, 2023

Dear Deng Yunlong:

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)*
K220673

Device Name
Sterile Silver Alginate Wound Dressing

Indications for Use *(Describe)*
Prescription Use:
Sterile Silver Alginate Wound Dressing (Rx only) is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites.

OTC:
Sterile Silver Alginate Wound Dressing (OTC) is first aid to help in minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds 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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510(K) Summary - K220673

This 510(K) Summary information is being submitted in accordance with 21 CFR 807.92.

I. SUBMITTER:

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Summary prepared：March 14th, 2023

II. SUBJECT DEVICE

Name of Device: Sterile Silver Alginate Wound Dressing
Classification Name: Dressing, Wound, Drug
FDA Panel: General and Plastic Surgery
Regulatory Class: Unclassified
Product Code: FRO

III. PREDICATE DEVICE

Predicate Device:	Silver Alginate Dressing (Prescription use), Antibacterial Alginate Wound Dressing (OTC use) (K202982)
Classification Name:	Dressing, Wound, Drug
FDA Panel:	General and Plastic Surgery
Regulatory Class:	Unclassified
Product Code:	FRO

IV. DEVICE DESCRIPTION

Sterile Silver Alginate Wound Dressing is a sterile, single-use dressing composed of calcium alginate and silver antibacterial agent. This highly absorbent dressing vertically absorbs wound exudate and release silver ions within the dressing in the presence of wound fluid to help reduce bacteria within the dressing. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment and allows intact removal. Based on in-vitro testing, the silver in the dressing inhibits bacterial growth in the dressing for up to seven days. No clinical benefit has been demonstrated regarding the antibacterial effectiveness of the silver component.

V. AVAILABLE MODELS

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

Table 1 Device model of Sterile Silver Alginate Wound Dressing

Model Name	Shape	Ref	Specification (cm)	Tolerance
Sterile Silver Alginate Wound Dressing	Sheet	YD05	5×5	±5%
		YD10	7.5×12	±5%
		YD15	10×10	±5%
		YD20	10×15	±5%
		YD25	10×20	±5%
		YD30	12.5×12.5	±5%
		YD40	15×15	±5%
		YD50	15×20	±5%
		YD60	15×25	±5%
		YD65	20×20	±5%
		YF01	2×5	±5%
		YF02	2×10	±5%
		YF03	2×30	±5%
		YF04	2×44	±5%
		YF05	3×30	±5%
		YF06	4×30	±5%

VI. INTENDED USE per 21 CFR 807.92(A)(5)

Prescription Use:

Sterile Silver Alginate Wound Dressing (Rx only) is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites.

OTC:

Sterile Silver Alginate Wound Dressing (OTC) is first aid to help in minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor burns.

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

The Sterile Silver Alginate Wound Dressing is compared with the predicate device Silver Alginate Dressing (Prescription use), Antibacterial Alginate Wound Dressing (OTC use) (K202982), manufactured by Winner Medical Co., Ltd.

The results are shown below in the Technological Characteristics Comparison Table:

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

Item	Subject Device (K220673)	Predicate Device (K202982)	Comparison
Classification Product Code	FRO	FRO	Same
Classification Regulation	Unclassified	Unclassified	Same
Indications for Use	Prescription Use: Sterile Silver Alginate Wound Dressing (Rx only) is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites. OTC: Sterile Silver Alginate Wound Dressing (OTC) is first aid to help in minor abrasions, minor cuts,	Prescription: Silver Alginate Dressing (Rx only) is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites. OTC: Antibacterial Alginate Wound Dressing (OTC) is first aid to help in minor abrasions, minor cuts,	Same

	minor lacerations, minor scrapes, minor scalds and minor burns.	minor lacerations, minor scrapes, minor scalds and minor burns.	
Mechanism	Alginate for absorbing liquid, silver present in the alginate for reducing bacteria in the dressing.	Alginate for absorbing liquid, silver present in the alginate for reducing bacteria in the dressing.	Same
Material	Calcium alginate, Carboxymethylcellulose sodium, Silver sodium zirconium hydrogenphosphate	Alginate and silver	Different
Antibacterial Duration	7 days	7 days	Same
Single Use	Yes	Yes	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
Sterilization	Gamma Irradiation SAL:10^{-6}	Radiation SAL:10^{-6}	Same
Free Swell Absorption Capacity	15.7g/g	14.2g/g	Different

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

Sterile Silver Alginate Wound Dressing 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 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 Sterile Silver Alginate Wound Dressing complies with the following standards:

Liquid absorbency EN 13726-1-2002
Loss on Drying: USP <731>
pH Value: USP <791> pH
Antimicrobial Efficacy: AATCC 100-2019
Minimum Bacteriostatic Concentration 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 Sterile Silver Alginate Wound Dressing is as safe, as effective, and performs as well as or better than the legally marketed predicate device Silver Alginate Dressing (Prescription use), Antibacterial Alginate Wound Dressing (OTC use) (K202982).