May 24, 2024

Foshan United Medical Technologies, Ltd.
Albert Rego
Regulatory Consultant
Southern Medical Devices Industrial Park
89 Taoyuan East Road, Shishan, Nanhai
Guangdong Province, 528225
China

Re: K233111
Trade/Device Name: ALGS2 Ag Alginate Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 9, 2024
Received: April 9, 2024

Dear Albert Rego:

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.

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) 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 Infection Control
and 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233111

Device Name
ALGS2 Ag Alginate Wound Dressing

Indications for Use *(Describe)*
Rx Only

Under the supervision of a healthcare professional, ALGS2 Ag Alginate Wound Dressing may be used for the management of acute and chronic, partial and full thickness wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, traumatic wounds, partial thickness burns.

For Over-the-Counter use (Pad Configurations), ALGS2 Ag Alginate Wound Dressing may be used for:
* 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
(As required by 21 CFR 807.92)

I. **SUBMITTER:** Foshan United Medical Technologies Ltd
Southern Medical Devices Industrial Park,89 Taoyuan East Road,
Shishan, Nanhai, Foshan,Guangdong Province,
528225, P.R. China

Contact Person: Albert Rego, Ph.D Inc.
Phone: (949) 770-8710

Date Prepared: May 10, 2024

II. DEVICE:

Trade Name: ALGS2 Ag Alginate Wound Dressing
Common Name: Dressing, Wound Dressing
Classification Name: Unclassified
Regulatory Class: Unclassified
Classification Product Code: FRO
Device Class Unclassified
Classification Panel General and Plastic Surgery

III. PREDICATE DEVICE:

	PREDICATE
510(k) Number:	K172570
Product Name:	ALGS6 Ag Alginate Wound Dressing
Manufacturer:	Foshan United Medical Technologies Ltd

IV. DEVICE DESCRIPTION:
ALGS2 Ag Alginate Wound Dressing is a soft, highly absorbent, sterile, single use, nonwoven (Rx version pad or ribbon, OTC version pad only) dressing composed of calcium alginate and 0.95% ionic silver which allows for a maximum of 18 mg of silver for a 4 inch x 4 inch dressing. The silver present in the dressing is to prevent or inhibit growth of bacteria within the dressing. The dressing absorbs wound fluid and creates a soft and cohesive gel which conforms to the wound surface and assists in maintaining a moist environment. The ALGS2 Ag Alginate Wound Dressing helps maintain a moist wound environment which is conducive to wound healing.
The ALGS2 Ag Alginate Wound Dressing is individually packaged in foil pouches and terminally sterilized by gamma radiation.

V. INDICATIONS FOR USE

Rx Only (Pad and Ribbon Configurations)

Under the supervision of a healthcare professional, ALGS2 Ag Alginate Wound Dressing may be used for the management of acute and chronic, partial and full thickness wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, traumatic wounds, partial thickness burns.

For Over-the-Counter use (Pad Configuration)

ALGS2 Ag Alginate Wound Dressing may be used for

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison of the subject device to the predicate device is provided in the tables below. The information provided in this premarket notification demonstrates the subject device is substantially equivalent to the predicate device.

Comparison to Predicate Device			
Parameter	**Subject Device** **ALGS2 Ag Alginate Wound Dressing**	**Predicate Device** **ALGS6 Ag Alginate Wound Dressing**	**Substantially Equivalent or Not Substantially Equivalent**
510(k) Number **Decision Date**	K233111	K172570	N/A
Manufacturer	Foshan United Medical Technologies Ltd	Foshan United Medical Technologies Ltd	N/A
Product Code	FRO	FRO	N/A

Comparison to Predicate Device			
Parameter	**Subject Device** **ALGS2 Ag Alginate Wound Dressing**	**Predicate Device** **ALGS6 Ag Alginate Wound Dressing**	**Substantially Equivalent or Not Substantially Equivalent**
Indications for Use	**Rx Only (Pad and Ribbon Configurations)** Under the supervision of a healthcare professional, ALGS2 Ag Alginate Wound Dressing may be used for the management of acute and chronic, partial and full thickness wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, traumatic wounds, partial thickness burns. **For Over-the-Counter use (Pad Configuration)** ALGS2 Ag Alginate Wound Dressing may be used for • Minor Abrasions • Minor Lacerations • Minor cuts • Minor scalds and burns	**Rx Only (Pad and Ribbon Configurations)** Under the supervision of a healthcare professional, ALGS6 Ag Alginate Wound Dressing may be used for management of acute and chronic, partial and full thickness wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, traumatic wounds, first and second degree burns. **For Over-the-Counter Use (Pad Configuration):** ALGS6 Ag Alginate Wound Dressing (K172570) may be used for: - Minor Abrasions - Minor Lacerations - Minor cuts - Minor scalds and burns	Substantially Equivalent
Intended Use	Intended for prescription use in the management of acute and chronic, partial and full thickness wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, traumatic wounds, partial thickness burns. Also intended for over-the-counter use for minor abrasions, minor lacerations, minor cuts, minor scalds and minor burns.	Intended for prescription use in the management of acute and chronic, partial and full thickness wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, traumatic wounds, first and second degree burns. Also intended for over-the-counter use for minor abrasions, lacerations cuts, scalds and burns.	Substantially Equivalent
Device Design	Highly absorbable, single layer, needle punched non-woven pad or ribbon dressing that can be cut or folded.	Highly absorbable, single layer, needle punched non-woven pad or ribbon dressing that can be cut or folded.	Substantially Equivalent
Mechanism of Action	Conformable, absorbent hydrophilic dressing that forms a soft, cohesive gel on contact with wound exudate which maintains a moist environment for optimal wound healing; ionic silver provides an antibacterial effect to prevent the growth of bacteria within the dressing.	Same	Substantially Equivalent

Comparison to Predicate Device			
Parameter	**Subject Device** **ALGS2 Ag Alginate Wound Dressing**	**Predicate Device** **ALGS6 Ag Alginate Wound Dressing**	**Substantially Equivalent or Not Substantially Equivalent**
Antibacterial Material	Ionic silver	Ionic Silver	Substantially Equivalent
Antibacterial Activity	Greater than 4 Log Reduction	Greater than 4 Log Reduction	Substantially Equivalent
Hydrophilic Material	Alginate	Alginate	Substantially Equivalent
Method of Affixation	Covered and secured with an appropriate secondary dressing	Same	Substantially Equivalent
Wear Time per Dressing	Up to 7 days	Up to 7 days	Substantially Equivalent
Integral Removal	Yes	Same	Substantially Equivalent
Single Use	Yes	Same	Substantially Equivalent
Sterilization	Gamma radiation (SAL 10^{-6})	Same	Substantially Equivalent
Primary Packaging	Foil pouch	Same	Substantially Equivalent

Summary

As shown in the comparison table above and listed in the similarities table below, the Indications for Use, intended use, general design characteristics, mechanism of action, antibacterial material and antibacterial activity are substantially equivalent to those of the designated previously marketed medical devices. In addition, both subject and predicate devices are single use, biocompatible, have the same packaging, provided sterile using gamma radiation, and have substantially equivalent absorbency and maximum silver release over 7 days within the dressing. Both subject and predicate devices have the same gelling properties in which the absorption of exudate forms a soft cool gel which maintains a moist environment for optimal wound healing.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

SUMMARY OF BIOCOMPATIBILITY TESTS AND RESULTS

TEST	METHOD
Cytotoxicity Test	ANSI/AAMI/ISO 10993-5 Tests for Cytotoxicity, *In Vitro* Method
ISO Guinea Pig Maximization Sensation Test (Sensitization Test)	ISO 10993-10 Test for Irritation and Sensitization
ISO Intracutaneous Reactivity (Irritation Test)	ISO 10993-10 Test for Irritation and Sensitization
Material Mediated Pyrogenicity (Pyrogen Test)	ISO 10993-11, per USP <151> Test for Pyrogenicity Potential
Acute Systemic Toxicity (Toxicity Test)	ISO 10993-11 Tests for Acute Exposure Systemic Toxicity Potential
Subchronic [Subacute Toxicity] (Repeat Exposure Test)	ISO 10993-11 Test to Discover The Effects a Material With Repeat Exposure Would Have On a Patient
Implantation Effects (Wound Healing Study)	ISO 10993-6 Test for local effects after implantation (2016)
Bacterial Endotoxins Test	USP 43 <85> Bacterial Endotoxins Test

Performance Testing - Bench

COMPONENT (NAME AND PART NUMBER/DRAWING NUMBER)	MATERIAL DESCRIPTION (TRADE AND GENERIC NAME)	MANUFACTURER (NAME, CITY AND STATE)	PATIENT CONTACT?	TEST RESULTS
Wound Dressing	Silver Alginate	Foshan United Medical Technologies (China)	Direct	Weight/Dimensions Absorbency Moisture Content Acidity Silver Content Heavy Metal Analysis Evaluation of Antibacterial Effectiveness

VIII. CONCLUSIONS

Based on the comparison of intended use and technological characteristics with the predicate device, the subject device, the ALGS2 Ag Alginate Wound Dressing is substantially equivalent to the predicate device.