May 11, 2018

Foshan United Medical Technologies, Ltd.
% Albert Rego
Albert Rego, Ph.D. Inc.
27001 La Paz Road, Suite #314
Mission Viejo, California 92691

Re: K172570
Trade/Device Name: ALGS6 Ag Alginate Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 9, 2018
Received: April 12, 2018

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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K172570

Device Name
ALGS6 Ag Alginate Wound Dressing (Pad and Ribbons Configurations)

Indications for Use *(Describe)*
Rx Only
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 bums.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K172570

Device Name
ALGS6 Ag Alginate Wound Dressing (Pad Configuration)

Indications for Use *(Describe)*
For Over-the-Counter use, ALGS6 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.

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K172570

510(k) Summary

1. Submission Sponsor

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Una Chen, Regulatory Affairs Manager

2. Submission Correspondent

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3. Date Prepared

July 31, 2017

4. Device Identification

Trade/Proprietary Name:	ALGS6 Ag Alginate Wound Dressing
Common/Usual Name:	Dressing, Wound, Drug
Classification Name:	Unclassified
Classification Regulation:	Unclassified
Product Code:	FRO
Device Class:	Unclassified
Classification Panel:	General and Plastic Surgery

5. Predicate Device

K121275 AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber, ConvaTec Inc

6. Reference Device

K162508 KerraCel Ag Gelling Fiber Silver Dressing

7. Device Description

ALGS6 Ag Alginate Wound Dressing is a highly absorbent, sterile, single use, nonwoven (Rx version pad or ribbon, OTC version pad) dressing composed of calcium alginate fiber, Lyocell fiber and 1.7% ionic silver which allows for a maximum of 30.6 mg of silver for a 4-inch x 4-inch dressing (0.306 mg per square centimeter). Silver is present in the dressing as a preservative to prevent or inhibit growth of bacteria within the dressing. The dressing absorbs high amounts of wound fluid and the bacteria contained in the wound fluid. The absorbed wound fluid in the dressing creates a soft and cohesive gel which assists in maintaining a moist environment. The moist wound healing environment and control of dressing bacteria supports the body's healing process.

8. Indication for Use

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 may be used for:

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

9. Comparison to Predicate

The intended use, device design, mechanism of action, material and performance testing of ALGS6 Ag Alginate Wound Dressing, as designed and manufactured, are determined to be substantially equivalent to the predicate device, ConvaTec's AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber, K121275. The differences between the ALGS6 Ag Alginate Wound Dressing and the predicate device do not raise different questions regarding its safety and effectiveness.

Exciton's KerraCel Ag Gelling Fiber Silver Dressing (K162508) has been identified as the Reference Device as K162508. It is also a gelling fiber dressing impregnated with silver and its silver content is the same as that for the subject device.

Parameter	Subject Device ALGS6 Ag Alginate Wound Dressing	Predicate Device AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber, ConvaTec Inc	Substantially Equivalent or Not Substantially Equivalent
510(k) Number Decision Date	K172570	K121275	N/A
Manufacturer	Foshan United Medical Technologies Ltd	ConvaTec	N/A
Product Code	FRO	FRO	Substantially Equivalent
Indications for Use	**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 may be used for • Minor Abrasions • Minor Lacerations • Minor cuts • Minor scalds and burns	AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber 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 dlehisced 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 surgicaliy debrided and donor sites;- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma; - Painful wounds; -Infected wounds **For Over-the-Counter Use:** AQUACEL™Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber (K121275) may be used for: - Abrasions - Lacerations - Minor cuts - Minor 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, two layers of ionic silver impregnated sodium carboxymethylcellulose stitched together with strengthening fibers, needle punched non-woven pad dressing that can be cut or folded.	Substantially Equivalent

Parameter	Subject Device ALGS6 Ag Alginate Wound Dressing	Predicate Device AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber, ConvaTec Inc	Substantially Equivalent or Not Substantially Equivalent
Mechanism of Action	Conformable, highly 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 inhibits bacterial colonization of the dressing.	Same	Substantially Equivalent
Antibacterial Material	Ionic silver	Ionic Silver	Substantially Equivalent
Antibacterial Effectiveness within the Dressing	Greater than 4 log reduction for 8 organisms (4 gram positive, 4 gram negative)	Log reduction for 3 organisms (1 gram positive, 1 gram negative , 1 fungi) and Zone of Inhibition for 19 organisms	Substantially Equivalent
Hydrophilic Material	Alginate	Sodium carboxymethylcellulose	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 7-14 days	Substantially Equivalent
Integral Removal	Yes	Same	Substantially Equivalent
Single Use	Yes	Same	Substantially Equivalent
Biocompatible	Yes	Same	Substantially Equivalent
Sterilization	Gamma radiation (SAL 10^{-6})	Same	Substantially Equivalent
Primary Packaging	Foil pouch	Same	Substantially Equivalent

a) Summary of Technologies Characteristics

ALGS6 Ag Alginate Wound Dressing consists of alginate fiber with ionic silver and some structure material (Lyocell fibers). Alginate forms gel when in contact with wound fluid. The predicate device consists of carboxyethyl cellulose fiber impregnated with ionic silver. The predicate device also contains some structure material (Tencel fiber). Carboxyethyl cellulose fiber gels when in contact with wound fluid. The primary function of both devices is absorption of wound exudates and moist wound healing. Differences in process do not affect the safety and efficacy of the device.

b) Summary of Performance Data

To verify that device design met its functional performance and safety requirements, representative samples of the device underwent testing including bench testing (weight and dimensions, absorbency, moisture content, pH, silver content, silver release, effective concentration, antibacterial effectiveness within the dressing), biocompatibility testing (irritation, sensitization, acute systemic toxicity, animal wound healing study, pyrogenicity testing, subchronic systemic toxicity study), packaging testing (pouch seal and transportation), sterilization validation testing, and shelf life stability testing (real time).

c) Wound Healing Study

ALGS6 Ag Alginate Wound Dressing (subject device) generally was observed to produce wound healing that was similar to AQUACEL ® Ag EXTRA™ (the predicate device) both macroscopically and microscopically. The ALGS6 Ag Alginate Wound Dressing does not cause any delay in wound healing in comparison to the predicate device.

10. **Conclusion:**
    Foshan United Medical Technologies Ltd considers the ALGS6 Ag Alginate Wound Dressing to be substantially equivalent to the predicate device. This conclusion is based upon comparison of the subject device's similarities, and differences in intended use, design, mechanisms of action, technology, and performance testing data.