June 17, 2020

Zhejiang Longterm Medical Technology Co., Ltd.
% Claudia Zsang
Director if Regulatory Affairs
Zhenjiang Longterm Medical Technology Co., Ltd.
No. 493 North Huancheng Road, Morgan Mountain National High-
Tech District
Deqing, Zhejiang 313200
China

Re: K192478
Trade/Device Name: LT Antibacterial Alginate with Silver Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 7, 2020
Received: May 19, 2020

Dear Claudia Zsang:

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,

Anjana Jain, 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)*

K192478

Device Name
LT Antibacterial Alginate with Silver Dressing

Indications for Use *(Describe)*

LT Antibacterial Alginate with Silver Dressing is used for management acute and chronic wounds, partial and full thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, pressure ulcers, donor and graft sites, surgical wounds, traumatic wounds, first and second-degree burns.
LT Antibacterial Alginate with Silver Dressing is intended for external use only.

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

1 The 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807. 92(c).

Date Prepared: June 17, 2019

Applicant: Zhejiang Longterm Medical Technology Co., LTD
No. 493 North Huancheng Road, Mogan Mountain National High-Tech District, Deqing Zhejiang, CHINA 313200

Official Correspondent: Claudia Zsang
Claudia.zsang@gmail.com

Phone Number: 416-276-9555

Device Name: LT Antibacterial Alginate with Silver Dressing

Common Name: Dressing, Wound, Drug

FDA Panel: General and Plastic Surgery

Product Code: FRO

Class: Unclassified

Predicate Devices:

K172570	ALGS6 Ag Alginate Wound Dressing (Foshan United Medical Technologies, Ltd.)
K053590	Silverlon CA Calcium Alginate Dressing-Antibacterial Silver (Argentum LLC)

2 Device Description:

LT Antibacterial Alginate with Silver Dressing is an advanced wound care dressing composed of calcium alginate and silver salt (3.5%). The dressing forms a gel when absorbs wound fluid to provide a moist environment and allows intact removal. When in contact with wound fluid, silver ions within the dressing inhibit bacterial growth in the dressing. LT Antibacterial Alginate with Silver Dressing is available in pad and ribbon configurations and various sizes. The pad is used to cover and protect the wound bed and the ribbon is used to pack the wound with cavity.

LT Antibacterial Alginate with Silver Dressing can be cut and layered for various wound shapes and types.

The device is available in the following configurations:

Product Code	Size(cm x cm)
SAD5301	5 x 5
SAD5304	10 x 10
SAD5306	10 x 20
SAD5312	15 x 20
SAD5315	20 x 20
SAD5405	2 x 30
SAD5407	2 x 40

3 Indications for Use:

LT Antibacterial Alginate with Silver Dressing is used for management acute and chronic wounds, partial and full thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, pressure ulcers, donor and graft sites, surgical wounds, traumatic wounds, first and second-degree burns.

LT Antibacterial Alginate with Silver Dressing is intended for external use only.

4 Substantial Equivalence

Parameter	Subject Device	Predicate Device #1	Predicate Device #2
510(k)#	K192478	K172570	K053590
Device name	LT Antibacterial Alginate with Silver Dressing	ALGS6 Ag Alginate Wound Dressing	Silverlon™ CA Calcium Alginate Dressing-Antimicrobial Silver
Classification Regulation	Unclassified	Identical	Identical
Product Code	FRO	Identical	Identical
Composition	Calcium alginate with Silver salt	Calcium alginate with Silver salt	Calcium alginate, nylon contact layer impregnated with metallic silver
Intended Use	LT Antibacterial Alginate with Silver Dressing is used for management acute and chronic wounds, partial and full thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, pressure ulcers, donor and graft sites, surgical wounds, traumatic wounds, first and second-degree burns. LT Antibacterial Alginate with Silver Dressing is intended for external use 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 burns.	Silverlon™ CA Advanced Antimicrobial Alginate Dressing is an effective barrier to microbial penetration for moderate to heavy exudating partial and full thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, donor and graft sites, traumatic and surgical wounds and 1st and 2nd degree bums. Silverlon™ CA Advanced Antimicrobial Dressing is indicated for external use only.
Device Category	Surface device, prolonged (>24hr to 30d)), in contact with breached or compromised skin	Identical	Identical

Device Design	Non-woven alginate with silver salt	Non-woven alginate with silver salt	Non-woven alginate with silver nylon contact layer
Antimicrobial agent	Ionic silver	Ionic silver	Ionic silver
Silver content	35 mg/g or 42mg/100cm^2	30.6mg/100cm^2	546 mg/100cm^2
Biocompatibility	Yes	Yes	yes
Sterilization	Gamma Irradiation	Gamma Irradiation	Irradiation
Sterility Assurance Level	SAL of 10^{-6}	SAL of 10^{-6}	SAL of 10^{-6}

5 Non-clinical Testing Summary:

The following tests were performed to support the substantial equivalence of the subject device:

Biocompatibility Testing:

- Cytotoxicity – ISO 10993-5:2009
- Irritation – ISO 10993-10:2010
- Sensitization – ISO 10093-10:2010
- Implantation – ISO 10993-6:2016
- Acute toxicity - ISO 10993-11:2017
- Sub-acute toxicity – ISO-11:2017
- Pyrogenicity -ISO 10993-11:2006/USP39-NF34 <151>

Bench testing:

- 4-log Antibacterial activity test (AATCC 100) against gram-negative, gram-positive, and yeast for up to 7 days.
- MEC
- Silver content and elution
- Absorption
- MVTR
- Tensile strength
- Stability study
- Simulated transportation test

Animal testing:

- Porcine wound healing study

6 Clinical Testing:

No clinical testing was required to support substantial equivalence.

7 Conclusion:

The data provided demonstrates that there are no new questions of safety and effectiveness, and the subject device is substantially equivalent to the predicate device.