November 1, 2019

4L Health Co., Ltd.
Jackie Jian
President
No. 108, Dongxin Rd, DongJiang Hi-tech Dist.
Huizhou, 516000 China

Re: K190119
Trade/Device Name: Foryou NPWT Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 28, 2019
Received: October 1, 2019

Dear Jackie Jian:

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,

for Cynthia J. Chang, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190119

Device Name

Foryou NPWT Dressing Kit

Indications for Use *(Describe)*

Foryou NPWT Dressing Kit is intended to be used with Foryou NPWT Device to manage wounds through removal of fluids, and the NPWT system is indicated for patients who would benefit from a suction device, particularly as it may promote wound healing by removal of fluids, excess exudate, infectious material, and tissue debris.

Foryou NPWT Dressing Kit is indicated for use in patients with the following wounds: traumatic, dehisced wounds, partial-thickness burns, chronic wounds including pressure ulcers, diabetic foot ulcers and venous leg ulcers, acute wounds, flaps and grafts.

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. Submitter's Information

Company:	4L Health Co., Ltd.
Address:	No. 108, Dongxin Road, Dong Jiang Hi-tech Dist., Huizhou City, Guangdong, 516000, China
Registration number:	3009425221
Contact Person:	Jackie JIAN
Tel:	+86-752-5300546
E-mail:	info@ForyouNPWT.com

Date Prepared: October 31, 2019

2. Trade Name of the Device

Foryou NPWT Dressing Kit

3. Common or Usual Name

Negative Pressure Wound Therapy Dressing Kit

4. Classification Name

Classification Name:	Negative Pressure Wound Therapy Powered Suction Pump
Review Panel:	General & Plastic Surgery
Regulation Description:	Powered suction pump
Product Code:	OMP
Regulation Number:	21 CFR 878.4780
Regulation Class:	II

5. Predicate Device Information

Carilex VT Dressing Kits, Carilex Medical, K172725

6. Device Description

Foryou NPWT Dressing Kit is the wound dressing kit to be used with Foryou NPWT Device for negative pressure wound therapy. It consists of three key components: the foam dressing, the tube unit, and the transparent film. The components are kitted into medical pouch and sterilized, or individually packaged and sterilized. Foryou NPWT Dressing Kit is single-use and sterile. It is available in different sizes: small, medium, large and extra large. The foam dressing should not be used for more than 24 hours and should be replaced with other dressings compatible with Foryou NPWT pump as stated in the Foryou NPWT pump labeling.

7. Indications for Use

Foryou NPWT Dressing Kit is intended to be used with Foryou NPWT Device to manage wounds through removal of fluids, and the NPWT system is indicated for patients who would benefit from a suction device, particularly as it may promote wound healing by removal of fluids, excess exudates, infectious material, and tissue debris.

Foryou NPWT Dressing Kit is indicated for use in patients with the following wounds: traumatic, dehisced wounds, partial-thickness burns, chronic wounds including pressure injuries, diabetic foot ulcers and venous leg ulcers, acute wounds, flaps and grafts.

8. Technological Comparison to Predicate Device

The comparison between Proposed Device and Predicate Device is as follows:

Elements of Comparison	Proposed Device	Predicate Device
Device Name	Foryou NPWT Dressing Kit	Carilex VT Dressing Kits
510K number	K190119	K172725
Manufacturer	4L Health Co., Ltd	Carilex Medical, Inc.
Classification	Class Ⅱ	Class Ⅱ
Regulation Number	21 CFR 878.4780	21 CFR 878.4780
Product Code	OMP	OMP
Target Area	For management of chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	For management of chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.
Review Panel	General & Plastic Surgery	General & Plastic Surgery
Prescription Medical Device	Yes	Yes
Compatible NPWT Pump	Foryou NPWT Device (OMP: K113236)	Carilex VT Device (OMP: K112853, K161410)
Intended Use	Foryou NPWT Dressing Kit is intended to be used with Foryou NPWT Device to manage wounds through removal of fluids, and the NPWT system is indicated for patients who would benefit from a suction device, particularly as it may promote wound healing by removal of fluids, excess exudates, infectious material, and tissue debris.	Carilex VT Dressing Kits is intended to be used with the Carilex VT device (S1 series) to manage wounds through removal of fluids, and the NPWT system is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of fluids, excess exudates, infectious material, and tissue debris.
Indications for Use	Foryou NPWT Dressing Kit is intended to be used with Foryou NPWT Device to manage wounds through removal of fluids, and the NPWT system is indicated for patients who would benefit from a suction device, particularly as it may promote wound healing by removal of fluids, excess exudates, infectious material, and tissue debris. Foryou NPWT Dressing Kit is indicated for	Carilex VT Dressing Kits is intended to be used with the Carilex VT device (S1 series) to manage wounds through removal of fluids, and the NPWT system is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of fluids, excess exudates, infectious material,

Elements of Comparison	Proposed Device	Predicate Device
	use in patients with the following wounds: traumatic, dehisced wounds, partial-thickness burns, chronic wounds including pressure injuries, diabetic foot ulcers and venous leg ulcers, acute wounds, flaps and grafts.	and tissue debris. The Carilex VT Dressing Kits is indicated for use for patients with the following wounds: Traumatic Dehisced wounds Partial-thickness burns Chronic wounds including pressure ulcers, diabetic foot ulcers and venous leg ulcers Acute wounds Flaps and grafts
Contraindications	Presence of Necrotic Tissue Malignancy Untreated Osteomyelitis Untreated Malnutrition Exposed Arteries, Veins, Nerves, or Organs Use Over Anastomotic Sites Use in Non-enteric and Unexplored Fistulas, as well for Use Over Exposed Bone or Tendon	Presence of Necrotic Tissue Malignancy Untreated Osteomyelitis Untreated Malnutrition Exposed Arteries, Veins, Nerves, or Organs Use Over Anastomotic Sites Use in Non-enteric and Unexplored Fistulas, as well for Use Over Exposed Bone or Tendon
Technology Principle of Operation	Foryou NPWT Dressing Kit is used with Foryou NPWT Device to manage wound with negative pressure and removal of exudate.	Carilex VT Dressing Kits is intended to be used with the Carilex VT device (S1 series) to manage wounds through removal of fluids.
User	Healthcare professional only	Healthcare professional only
Single Use or Reusable	Single Use	Single Use
Sterile	YES	YES
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Biocompatibility	All components comply with ISO 10993	All components comply with ISO 10993
Packaging	Components are kitted into medical pouch and sterilized, or individually packaged and sterilized.	Individually packaged and sterilized components are kitted into Tyvek pouch.
Shelf Life	3 years	2 years
Dressing Kits Components	Black Foam Dressing Transparent Film Tube Unit (Composed of drainage tube, port, circle drape, clip, and strap)	Black Foam, Film Drape, Port Set (composed of Circle Drape, Connecting Tube, Port, Clip, Lockable Connector)
Foam Dimension	Small: 75x100x30 mm Medium: 125x180x30 mm Large: 150x260x30 mm Extra Large: 250x350x15 mm	Small: 80x100x30 mm Medium: 125x200x30 mm Large: 150x250x30 mm
Foam Material	Reticulated Flexible Polyurethane Foam	Reticulated Flexible Polyether Based Polyurethane Foam
Film Dimension	300x200mm , 350x320mm	203x305mm
Film Quantity	Extra Large: 350x320mm, 4 pcs Large Kits: 350x320mm, 2 pcs Medium Kits: 350x320mm, 2 pcs Small Kits: 300x200mm, 1 pc	Large Kits: 3 pcs Medium Kits: 2 pcs Small Kits: 1 pc
Film Material	Polyurethane Film Coated with Acrylic Adhesive	Polyurethane Film Coated with Acrylic Adhesive
Tube Unit Material	Polyvinyl chloride drainage tube, Thermoplastic urethane port, Polyurethane film,	Unknown

Elements of Comparison	Proposed Device	Predicate Device
	Acrylonitrile butadiene styrene clip, Paper&polyethylene terephthalate strap.	
Packaging Material	83g coated medical paper pouch	Unknown

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following tests were performed to determine substantial equivalence:

a. Package Integrity Tests

The components of Foryou NPWT Dressing Kit are kitted into medical pouch and sterilized, or individually packaged and sterilized.

The pouch tests have been done during the validation of the sterilization cycle. The tests results show that the pouch can meet the requirements of package integrity.

b. Shelf-life Test

In accordance with ASTM F1980-16, the stability of the Proposed Device was established from the results of the testing data from an accelerated aging test. Based on the evaluation of the results of the testing data, the Shelf life of Foryou NPWT Dressing Kit is 3 years.

c. Biocompatibility Tests

The biocompatibility tests were performed with Foryou NPWT Dressing Kits, which showed that Foryou NPWT Dressing Kits are biocompatible for the intended use for a ‘limited’ contact duration.

d. Performance tests

The Foryou NPWT Dressing Kit met all pre-defined acceptance criteria and passed the tests for pressure conduction and exudate removal.

10. Clinical Test

Clinical tests were not performed.

11. Conclusion

The proposed device is substantially equivalent to the predicate device. The differences between the proposed device and the predicate device do not raise different questions regarding its safety and effectiveness.