August 9, 2018

Carilex Medical, Inc.
Henry Kao
RA Specialist
No. 77 Keji 1st Rd., Guishan Dist.
Taoyuan City, Taiwan 333

Re: K173407
Trade/Device Name: VT - 100, VT - 200
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: July 6, 2018
Received: July 9, 2018

Dear Henry Kao:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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)*

K173407

Device Name

Carilex VT · 100/VT · 200

Indications for Use *(Describe)*

Carilex VT · 100/VT · 200 is indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids and excess exudate, infectious material, and tissue debris which may promote wound healing.

The VT · 100/VT · 200 suction therapy unit is indicated on use with 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

The assigned 510(k) number is: K173407

1. Submitter's Information

Carilex Medical, Inc.
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Registration Number: 9710603
Contact: Henry Kao
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Date Summary Prepared: October 27, 2017

2. Trade Name of the Device: Carilex VT・100 & VT・200

3. Common or Usual Name: Powered Suction Pump

4. Classification Name: Negative Pressure Wound Therapy Powered Suction Pump

Regulation Number:	878.4780
Product Code:	OMP
Panel:	General & Plastic Surgery

5. Predicate Device Information:

VOLTERA Powered Suction Pump, S1001-3 Series, K112853

6. Device Description

Carilex VT・100 and VT・200 are suction pumps with collection canisters for negative pressure wound therapy. The VT・100 and VT・200 are modified from their precursor VOLTERA Powered Suction Pump, S1001-3 Series (K112853). The pump is connected to the wound dressing via a tube connected to a disposable canister. The devices provide negative pressure wound therapy to the wound at a range of pressure settings and removes exudates from the wound site to the disposable canister. The devices can operate either by a mains power supply or internal battery. The VT・200 is developed with technology and components that are almost identical to VT・100, but for marketing differentiation it is designed with a new outer case which contains extra room to allow incorporation with different types of air compressors in the future.

7. Intended Use

Carilex VT・100/VT・200 is indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids and excess exudate, infectious material, and tissue debris which may promote wound healing. The VT・100/VT・200 suction therapy unit is indicated on use with 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.

8. Technological Comparison to Predicate Devices:

Item	Proposed Devices		Predicate Device
Device Name	VT・200	VT・100	VOLTERA Powered Suction Pump
Model	S1002-0012	S1001-0032	S1001-3 Series
Classification	Class II	Class II	Class II
Code for Federal Regulations	878.4780	878.4780	878.4780
Product Code	OMP	OMP	OMP
Prescription Medical Device	YES	YES	YES
Compatible NPWT Dressing	DeRoyal Foam Kits (K112458)	DeRoyal Foam Kits (K112458)	DeRoyal Foam Kits (K112458)
Intended Use	Carilex VT・200 is indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids and excess exudate, infectious material, and tissue debris which may promote wound healing.	Carilex VT・100 is indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids and excess exudate, infectious material, and tissue debris which may promote wound healing.	The VOLTERA Powered Suction Pump, S1001-3 Series is indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids and excess exudate, infectious material, and tissue debris which may promote wound healing.

Indications for Use	The VT・200 suction therapy unit is indicated on use with 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	The VT・100 suction therapy unit is indicated on use with 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	The VOLTERA suction pump is indicated on use with 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 ➢ Unexplored or non-enteric fistulas ➢ Exposed bone or tendons	➢ Presence of necrotic tissue ➢ Malignancy ➢ Untreated Osteomyelitis ➢ Untreated malnutrition ➢ Exposed arteries, veins, nerves, or organs. ➢ Use over anastomotic sites ➢ Unexplored or non-enteric fistulas ➢ Exposed bone or tendons	➢ Presence of necrotic tissue ➢ Malignancy ➢ Untreated Osteomyelitis ➢ Untreated malnutrition ➢ Exposed arteries, veins, nerves, or organs. ➢ Use over anastomotic sites
Suction Capacity	9.5 Liter / min	2.5 Liter / min	2.5 Liter / min
Max. Vacuum	-200 mmHg	-200 mmHg	-200 mmHg
Power Input	AC 100-240V / 50-60 Hz	AC 100-240V / 50-60 Hz	AC 100-240V / 47-63 Hz
Power Output	DC 9.1V / 3.3A	DC 9.1V / 3.3A	DC 9V / 3A
Battery Type	Lithium-ion	Lithium-ion	Lithium-ion
Operating Time (Battery)	At least 24 hours, depend on use	At least 24 hours, depend on use	At least 24 hours, depend on use
Dimensions	18 x 17.5 x 9 cm	18 x 17 x 9 cm	17 x 16 x 9 cm
Weight	1.35 kg	1.35 kg	1.35 kg
Operating Mode	Continuous & Intermittent	Continuous & Intermittent	Continuous & Intermittent
Canister	300/500 ml	300/500 ml	300/800 ml

Life-time	3 years	3 years	3 years

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

The following tests were performed to determine substantial equivalence:

AAMI/ANSI ES60601-1:2005/(R)2012+A1:2012, C1:2009/(R)2012+A2:2010/(R)2012
Medical Electrical Equipment – Part 1:General Requirements for basic safety and essential performance

IEC 60601-1-2:2007
Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests

Performance/Comparison Testing of VT・100/VT・200 with the predicate. The pumps met all pre-determined acceptance criteria and passed the tests (suction pressure, fluid removal rate, alarm functionality).

10. Discussion of Clinical Tests Performed

Clinical tests were not performed.

11. Conclusion

After analyzing intended use, indications for use, technology, bench test report, shelf-life test reports, software documents, and EMC and electrical safety test reports, it can be concluded that Carilex VT・100 and VT・200 are substantially equivalent to the predicate device (K112853).