DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

October 13, 2016

Carilex Medical, Inc.
% Maria Griffin
Senior Consultant
Mdi Consultants, Inc.
55 Northern Blvd.
Great Neck, New York 11021

Re: K161410
Trade/Device Name: VT·One, VT·One 60days
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 8, 2016
Received: September 9, 2016

Dear Maria Griffin:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161410

Device Name
Carilex VT·One/VT·One 60days

Indications for Use *(Describe)*
Carilex VT·One/VT·One 60days is indicated for patients who benefit from removal of fluids and excess exudates, infectious material, and tissue debris, which may promote wound healing. The VT·One/VT·One 60days 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.

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510(K) SUMMARY

The assigned 5l0(k) number is: K161410

1. Submitter's Identification:

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Date Summary Prepared: May 20, 2016

2. Trade Name of the Devices: Carilex VT·One/ VT·One 60days

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·One and VT·One 60days are suction pumps with collection canisters for negative pressure wound therapy. Carilex VT·One and VT·One 60days are modified from its precursor VOLTERA Powered Suction Pump, S1001-3 Series (K112853), and they are smaller, portable and lighter in weight. The pump is connected to the wound dressing via a tube connected to a disposable canister. The device provides 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 device can operate either by a mains power supply or internal battery.

The intended use, performance, and technology for Carilex VT·One and VT·One 60days are mostly identical. However, the VT·One 60days is programmed to stop working after 60 days of use and will not re-start after this time. This feature makes VT·One 60days a single patient use NPWT pump that has a lifetime of 60 days; while VT·One is a durable medical device with a minimum lifetime of 3 years.

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7. Intended Use:

Carilex VT·One/VT·One 60days is indicated for patients who benefit from removal of fluids and excess exudates, infectious material, and tissue debris, which may promote wound healing. The VT·One/VT·One 60days 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·One	VT·One 60days	VOLTERA Powered Suction Pump, S1001-3 Series
Classification	Class II		Class II
Code for Federal Regulations	878.4780		878.4780
Prescription Medical Device	YES		YES
Model	S1004-0012	S1004-0022	S1001-3 Series
Compatible NPWT Dressing	DeRoyal Foam Kits (K112458)		DeRoyal Foam Kits (K112458)
Intended Use	Carilex VT·One/VT·One 60days is indicated for patients who benefit from removal of fluids and excess exudates, 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·One/ VT·One 60days 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		➢ Presence of necrotic tissue ➢ Malignancy ➢ Untreated Osteomyelitis ➢ Untreated malnutrition ➢ Exposed arteries, veins, nerves, or organs. ➢ Use over anastomotic sites
Suction Capacity	0.8 Liter / min	0.6 Liter / min	2.5 Liter / min
Max. Vacuum	- 150 mmHg		- 200 mmHg
Power Input	AC 100-240V / 50-60 Hz		AC 110-240V / 47-63 Hz

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Power Output	DC 12V / 1.25A		DC 9V / 3A
Battery Type	Lithium ion		Lithium ion
Operating Time (Battery)	16 hours, depend on use		24~48 hours, depend on use
Dimensions	150 mm x 85 mm x 50 mm		170 mm x 160 mm x 90 mm
Weight	350g		1.35 kg
Operating Mode	Continuous & Intermittent		Continuous & Intermittent
Canister	150 ml		300 ml
Life-time	3 years	60days	3 years
Software Setting	Programmed to be repetitively used during lifetime	Programmed to stop working after 60 days	Programmed to be repetitively used during lifetime

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

The following tests were performed to determine substantial equivalence:

IEC60601-1:2005+COR1(2006)+COR2(2007)+AMD1(2012)
Medical Electrical Equipment – Part 1:General Requirements for basic safety and essential performance

IEC60601-1-2:2007
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·One/ VT·One 60days with the predicate. The pumps met all pre-determined acceptance criteria and passed the tests.

10. Discussion of Clinical Tests Performed:

Clinical tests were not performed.

11. Conclusions:

After analyzing intended use, indications for use, technology, bench test reports, shelf-life reports, and EMC and electrical safety tests, it can be concluded that Carilex VT·One/ VT·One 60days is substantially equivalent to the predicate device VOLTERA Powered Suction Pump, S1001-3 Series (K112853).