April 17, 2024

Carilex Medical, Inc.
% Aristotle Nafpliotis
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K231646
Trade/Device Name: Carilex VT • 200-i NX
Regulatory Class: Class II
Product Code: OMP
Dated: March 13, 2024
Received: March 13, 2024

Dear Aristotle Nafpliotis:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231646

Device Name
Carilex VT · 200-i NX

Indications for Use *(Describe)*
The "Carilex" VT · 200-i NX 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 device is not intended for home use. Wound irrigation/Instillation function is not intended for use in a homecare setting.

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

1. Submitter's Information

Carilex Medical, Inc.
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Taoyuan City, 333, Taiwan
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Email: Pauline.su@carilexmedical.com
Date Summary Prepared: Feb 15, 2023

2. Trade Name of the Device: Carilex VT·200-i NX

3. Regulation Name: Powered Suction Pump

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

Regulation Number:	21 CFR 878.4780
Product Code:	OMP
Panel:	General & Plastic Surgery

5. Predicate Device Information:

Carilex VT·100 and VT·200, S1001-3 Series, K173407
Cardinal Health, Sved®, K142916

6. Device Description

Carilex VT·200-i NX is a powered, portable suction device with battery backup that provides localized negative pressure wound therapy when used with the VT Dressing kits to remove body fluids, irrigation fluids, infectious material and tissue debris from the wound.

Carilex VT·200-i NX have shown that they may help promote the healing of several different kind of wounds via fluid removal. When in use, the vacuum air suction pump in the control unit suck the air from the wound through the connecting hose and dressing to create a negative pressure environment of the wound. The suction of the pump will help remove excess fluids from the wound. VT Dressing kits will be placed onto the wound by healthcare professional and a tube will be connected from the wound to the canister on the pump. After the dressing and tube are correctly applied and connected, turn on the VT·200-i NX device and set to the pressure setting that is prescribed by healthcare provider. The canister will then collect the excess fluid. This device is not intended for home use.

Carilex VT·200-i NX is an updated version of Carilex VT·100/VT·200 (K173407) via engineering change, and its software and hardware modifications are made to add instill function. The instillation mode is a

modified continuous mode, where wound irrigation solution is simultaneously infused during negative pressure suction to assist in wound cleaning and removal of infectious substances. There has been no change to the operating principle, mechanism of action or fundamental scientific technology of the predicate device. The Carilex VT·200-i NX is developed with technology and components that are almost identical to Carilex VT·100/ VT·200.

Carilex VT·200-i NX use the same collection canisters as predicate, VT·100, and VT·200 that are supplied non-sterile, single-use with a volume capacity of 300 ml, 500 ml or 1000ml. The canister is permanently sealed to minimize the potential of users coming into contact with exudates. Two tubes with two connector attached to its distal end is attached to the canister, and this connector which can be provided with or without lock feature attaches to the corresponding tubing included in the Carilex VT Dressing Kits.

7. Intended Use(s)

Carilex VT • 200-i NX is an integrated wound management system, indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids, including wound exudate, irrigation fluids, body fluids, infectious material and tissue debris which may promote wound healing. The device is not intended for home use. Wound irrigation/Instillation function is not intended for use in a homecare setting.

8. Indication for use

The "Carilex" VT · 200-i NX 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 device is not intended for home use. Wound irrigation/Instillation function is not intended for use in a homecare setting.

9. Technological Comparison to Predicate Devices:

According to the comparison table below, there were no clinically significant differences identified and some similar technical characteristics identified between proposed device (VT·200-i NX) and predicate device (VT·200 and Sved®). Therefore, it can be concluded that Carilex VT·200-i NX are substantially equivalent to the predicate device (K173407 and K142916).

Item	Proposed Devices	Predicate Device 1	Predicate Device 2
Company	Carilex Medical Inc.	Carilex Medical Inc.	Cardinal Health
Device Name	VT·200-i NX	VT·200	Sved®
Model	S1002-0062	S1002-0012	-

Item	Proposed Devices	Predicate Device 1	Predicate Device 2
FDA Clearance	N/A	K173407	K142916
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 Dressing	Carilex VT Dressing Kits (K172725)	DeRoyal Foam Kits (K112458)	Cardinal Health™ NPWT Dressing (K161418)
Intended Use	.Carilex VT·200-i NX is an integrated wound management system, indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids, including wound exudate, irrigation fluids, body fluids, infectious material and tissue debris which may promote wound healing. The device is not intended for home use. Wound irrigation/Instillation function is not intended for use in a homecare setting.	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.	The Cardinal Health NPWT SVED system is an integrated wound management system, indicated for the application of continual or intermittent negative pressure wound therapy to the wound as the device may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.
Indications for Use	The Carilex VT·200-i NX 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	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 SVED® NPWT System is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, surgical incisions following sutured or stapled closure, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

Item	Proposed Devices	Predicate Device 1	Predicate Device 2
	➢ Flaps and grafts The device is not intended for home use. Wound irrigation/Instillation function is not intended for use in a homecare setting.		
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	The SVED® is contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, or necrotic tissue with eschar present.
Suction Capacity	9.5 Liter / min	9.5 Liter / min	NA
Max. Vacuum	-200 mmHg	-200 mmHg	-150mmHg
Power Input	AC 100-240V / 50-60 Hz	AC 100-240V / 50-60 Hz	100-240VAC, 50-60Hz
Power Output	DC 9.1V / 3.3A	DC 9.1V / 3.3A	15VDC, 2Amp
Battery Type	Lithium-ion	Lithium-ion	NA
Operating Time (Battery)	At least 24 hours, depend on use	At least 24 hours, depend on use	up to 10.5 hours
Dimensions	18 x 17.5 x 9 cm	18 x 17.5 x 9 cm	7.6 x 2.8 x 7.1 in.
Weight	1.35 kg	1.35 kg	0.9kg (2.0 lb.)
Operating Mode	Continuous & Intermittent & Instill	Continuous & Intermittent	Continuous & Intermittent & Simultaneous irrigation technology
Pressure during instillation	higher pressure: -80 to -200 mmHg lower pressure: -20 to -80 mmHg	-	higher pressure: -50 or -120 or -150 mmHg lower pressure: -25 mmHg
Rate of fluid instillation	Max 200ml/hr	-	Set the drip rate per physician order.
Canister	300/500/1000 ml With double lumens	300/500/1000 ml With single lumen	300/500 ml
Sterile	Non-Sterile	Non-Sterile	Non-Sterile

Item	Proposed Devices	Predicate Device 1	Predicate Device 2
Life-time	3 years	3 years	3 years
Electrical Safety	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010(R)2012.	AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	IEC 60601-1
EMC	IEC 60601-1-2:2014, EN 60601-1-2:2015	IEC 60601-1-2:2007	IEC 60601-1-2

Operating Mode & Pressure setting

The general therapy modes, continuous and intermittent, of the all devices are the same, but proposed devices (VT·200-i NX) is with additional mode for instill. The instillation mode is a modified continuous mode, where wound irrigation solution is simultaneously infused during negative pressure suction to assist in wound cleaning and removal of infectious substances. This principle is similar to the predicate device 2 (Sved®) Simultaneous irrigation technology. The predicate device (SVED®) allows for the optional use of wound irrigation to the wound bed. During irrigation operation, the predicate device (SVED®) will provide higher pressure (-50 or -120 or -150 mmHg) and approximately -25 mmHg lower pressure.

Canister

The canister compatible with the proposed device (VT • 200-i NX) has undergone a mechanical design revision, incorporating additional tubing to accurately detect the pressure at the wound site.

EMC

The electric design of both device is the same, in addition, proposed devices (VT·200-i NX) is compliance with the most updated standards.

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

This submission is to provide an update to the existing cleared Carilex VT·100/ VT·200. The subject and predicate devices are based on the following same technical elements:

- Continuous and Intermittent treatment modes with the addition of instillation mode in the subject device
- Pressure sensing technology within the pump
- Available for use with 300cc and 500cc, 1000cc canisters
- Use AC and Rechargeable battery

The following technological differences exist between the subject and predicate devices:

- The updated Carilex VT·200-i NX has an updated indications for use to include the removal of irrigation fluids via the application of negative pressure. This better aligns the indications for use with the "OMP" regulation definition.
- The updated Carilex VT·200-i NX has had other enhancements including:
  - Canister with additional tubing to detect the pressure of wound site accuracy

- The Electronic Magnetic Compatibility testing has been performed to comply with IEC 60601-1-2:2014 standard. It does not raise any issue in safety and effectiveness.

11. Summary for Performance Testing

I. To demonstrate that the Carilex VT·200-i NX are substantially equivalent to the predicate, Carilex VT·100 and VT·200 Powered Suction Pump, S1001-3 Series (K173407), head to head simulated use testing has been conducted which demonstrate the overall system performance of Carilex VT·200-i NX.

Method 1	Compare suction pressure with no fluid introduced (air) under continuous and intermittent mode.
Method 2	Compare suction pressure and fluid removal rate with plasma introduced under continuous and intermittent mode.
Method 3	Compare suction pressure and fluid removal rate with Simulated Body Fluid (SBF) introduced under continuous and intermittent mode.
Method 4	Compare leakage alarm function under continuous and intermittent mode.
Method 5	Compare canister-full alarm function under continuous and intermittent mode.
Method 6	Compare blockage alarm function with default time delay (1 min) under continuous and intermittent mode.
Method 7	Test suction pressure and fluid removal rate with Normal saline introduced under instill mode.
Method 8	Test the possibility of pooling occurring at the simulates wound site under instill mode
Method 9	Test leakage indicator function under instill mode
Method 10	Test canister-full indicator function under instill mode
Method 11	Test blockage indicator function under instill mode

II. 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 60601-1-2:2014
Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility- Requirements and Tests

According to the results derived from the above tests, it can be concluded that Carilex VT·200-i NX are substantially equivalent to the predicate device Carilex VT·100 and VT·200 (K173407) in terms of generating suction pressure and removing fluids from wound model within specification.

III. Usability Testing
A usability study was conducted in accordance with IEC 62366:2015 and FDA guidance to evaluate the safety and effectiveness of the VT · 200-i NX under the intended user and conditions of use.

12. 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·200-i NX are substantially equivalent to the predicate device Carilex VT·100 and VT·200 (K173407) and Cardinal Sved® (K142916).