08/22/2024

Cork Medical
Antonio Williams
Quality/Regulatory Engineer
8000 Castleway Drive
Indianapolis, Indiana 46250

Re: K241061
Trade/Device Name: VERSA Negative Pressure Wound Therapy System (VCMPP-100)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP

Dear Antonio Williams:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 21, 2024. Specifically, FDA is updating this SE Letter due to incorrect contact address. The address listed in the original letter states the contact city and state as Indianapolis, Idaho. This should be changed to Indianapolis, Indiana as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yu-Chie Chiu, OHT4: Office of Surgical and Infection Control Devices, Assistant Director, yu-chieh.chiu@fda.hhs.gov.

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

August 21, 2024

Cork Medical
Antonio Williams
Quality/Regulatory Engineer
8000 Castleway Drive
Indianapolis, Idaho 46250

Re: K241061
Trade/Device Name: VERSA Negative Pressure Wound Therapy System (VCMPP-100)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 13, 2024
Received: May 24, 2024

Dear Antonio Williams:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241061

Device Name
VERSA Negative Pressure Wound Therapy System (VCMPP-100)

Indications for Use *(Describe)*
The VERSA Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.

The VERSA Negative Pressure Wound Therapy System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004) and the VERSA NPWT 100ml Canister.

The VERSA Negative Pressure Wound Therapy System is suitable for use in both a professional healthcare facility and home use environment.

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.

510(k)
Summary
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	Cork Medical, LLC
Company Address:	8000 Castleway Drive Indianapolis, IN 46250
Telephone:	317-361-4387
Fax:	866-271-2580
Establishment Registration Number	3010588638
Contact Person:	Antonio Williams Regulatory Engineer awilliams@corkmedical.com
Date Prepared:	04/17/2024

DEVICE NAME **807.92(a)(2)**

Trade Name	VERSA Negative Pressure Wound Therapy System (VCMPP-100)
Common/Usual Name:	VERSA NPWT System
Model Number	VCMPP-100
Classification Name:	Powered Suction Pump
Regulation Number:	21 CFR 878.4780
Product Code:	OMP
Device Class:	Class II
Panel:	General & Plastic Surgery
Reason for 510(k) Traditional	• Change the environment of use identified under K230677 for the VERSA NPWT System from a professional healthcare facility only to both professional healthcare facility and home use environment • Update Firmware - Firmware update will add a troubleshooting display that will cycle on the LCD

screen after the alarm condition occurs.

- Adding visual inspection instructions in both the Instruction for Use (IFU) and Quick Refence Guide (QRG) according to FDA Guidance:
- Added Illustrations to the IFU

PREDICATE DEVICE **807.92(a)(3)**

Company	Trade Name	510(k) Number
Cork Medical	Cork Medical VERSA Negative Pressure Wound Therapy System	K230677

DEVICE DESCRIPTION **807.92(a)(4)**

The Cork Medical VERSA Negative Pressure Wound Therapy System is designed to provide gentle powered suction to treat and promote wound healing by aiding in the removal of excess exudates, infectious material, and tissue debris. The single button design makes applying negative pressure wound therapy for patients and physicians without compromising the power and performance demanded for wound management.

The VERSA NPWT System interface utilizes a single membrane switch keypad to power the device and switch between continuous and intermittent therapy modes. One button power on and off the pump and the other button switches pressure settings from 75 mm/Hg and 125 mm/Hg continuous and a 10 second hold on this button switches the pump to a variable intermittent mode, unlike its predecessor Cork NPWT System which uses multiple buttons and menus to adjust settings.

The VERSA NPWT System includes a therapy pump, 100 ml collection disposable canister, and carrying bag. The VERSA NPWT System is only intended to be used with the Cork NPWT Wound Dressing Kit.

INDICATIONS FOR USE **807.92(a)(5)**

The VERSA Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.

The VERSA Negative Wound Therapy System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004) and the VERSA 100 ml Canister.

The VERSA Negative Wound Therapy System is suitable for use in both a professional healthcare facility and home use environment.

PREDICATE PRODUCT COMPARSION TABLE 807.92(a)(6)

	Subject Device	**Predicate Device**
Company	Cork Medical	Cork Medical
Device Name	VERSA Negative Pressure Wound Therapy System	VERSA Negative Pressure Wound Therapy System
510(k) Number	K241061	K230677
Regulation Number / Product Code	21 CFR 878.4780 / OMP	21 CFR 878.4780 / OMP
Indications for Use	The VERSA Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris. The VERSA Negative Wound Therapy System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004) and the VERSA 100 ml Canister. The VERSA Negative Wound Therapy System is suitable for use in both a professional healthcare facility and home use environment.	The VERSA Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris. The VERSA Negative Wound Therapy System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004) and the VERSA 100 ml Canister.
Features	No change	• Compact size • 2 continuous pressure settings of 75mm/Hg and 125 mm/Hg • Disposable batteries • Variable intermittent mode
Suction Capacity	No change	2 liters / minute
Maximum Vacuum Pressure	No Change	170 mm/Hg
Power Requirements	No Change	3 x 1.5 V (3 AA battery)
Battery Type	No Change	Li-ion
Dimensions	No Change	4.6” (H) x 2.4” (W) x 2.0” (D) - Device 4.6” (H) x 2.4” (W) x 3.0” (D) with Canister
Weight	No change	0.6 lb.
Reusable	No Change	Yes

Sterile	No Change	Non-sterile
Compliance	No Change	IEC 60601-1-2 ed 4.0 (2014-02) IEC 60601-1:2005, AMD1:2012 CSA C22.2#60601-1:2014 Ed.3 AAMI ES60601-1:2005+C1;A2:2010 IEC 60601-1-8:2006, AMD1:2012 for use in conjunction with IEC 60601-1:2005, AMD1:2012 IEC 60601-1-6:2010, AMD1:2013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 IEC 60601-1-11:2015 for use in conjunction with IEC 60601-1:2005, AMD1:2012
Storage & Shipping Conditions	No Change	-30ºC (-22ºF) without relative humidity control to 60ºC (140ºF) up to 90% relative humidity (non-condensing)
Environmental Conditions	No Change	Operating Temperature: 18ºC to 34ºC (65ºF to 94ºF) Operating Relative Humidity: 10% - 95% Operating Pressure: 700-hPA – 1060-hPA (10.15-atm – 15.37-atm) atmospheric pressure
Accessories	No change	*Canisters:* One canister size 100 ml Features: hydrophobic membrane filter, liquid solidifier *Wound Dressing Kit: Cork NPWT Wound Dressing Kit (K132004)* Bench Testing completed utilized accessories previously cleared on separate 510k applications to mimic the predicate device setting.

NONCLINICAL TESTS **807.92(b)(1)**

The VERSA Negative Pressure Wound Therapy System underwent bench performance testing and usability testing to demonstrate substantial equivalence to the predicate device. The bench performance tests conducted are:

- Block Alarm Testing
- Canister Full Alarm Testing
- Leak Alarm Testing
- Low Battery Alarm Testing

The testing results show the VERSA NPWT System functioned as safe and effective as the predicate device. The software modifications were developed, tested and assessed according to FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) and FDA-recognized standard: IEC 62304 Ed. 1.1 b:2015

The usability testing was conducted in accordance with the applicable guidelines listed in FDA Guidance Document: Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016) and in FDA-recognized standards: IEC 62366-1:2015+AMD1:2020 and ANSI/AAMI HE75:2009

CLINICAL TESTS **807.92(b)(2)**

No clinical testing required to support these 510(k) submissions. No clinical testing has been performed.

CONCLUSIONS **807.92(b)(3)**

The subject devices indications for use, fundamental technology and principles of operation are unchanged when compared to the predicate devices as cleared under K230677.

Minor changes between the subject and predicate device as cleared under K230677:

- Update Firmware
- Adding visual inspection instructions in the Instruction for Use (IFU)
- Add illustrations Quick Refence Guide (QRG) according to FDA Guidance for Home Use

The minor technological differences between the subject VERSA NPWT System provide additional safety features to further mitigate existing risks for the home use environment, do not significantly affect the effectiveness of the device and do not represent a major change in user tasks or interactions.

The subject device is as safe and effective as the predicate device. Thus, the subject VERSA NPWT System is substantially equivalent to its predicate.