December 6, 2023

Cork Medical
Antonio Williams
Quality/Regulatory Engineer
8000 Castleway Drive
Indianapolis, Indiana 46112

Re: K230677
Trade/Device Name: Cork Medical VERSA Negative Pressure Wound System (VCMPP-100)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: November 1, 2023
Received: November 6, 2023

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 (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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230677

Device Name
VERSA Negative Pressure Wound Therapy System

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).

The VERSA Negative Pressure Wound Therapy System is not intended for home use environments.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k)
Summary

807.92(c)

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

Company Name:	Cork Medical
Company Address:	8000 Castleway Drive Indianapolis, IN 46250
Telephone:	317-361-4387
Fax:	866-271-2580
Contact Person:	Antonio Williams
Date Prepared:	11/01/2023

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

Trade Name:	VERSA Negative Pressure Wound Therapy System
Common / Usual Name:	VERSA NPWT System
Classification Name:	Negative Pressure Wound Therapy Powered Suction Pump
Regulation Number:	21 CFR 878.4780
Product Code:	OMP
Device Class:	Class II
Panel:	General & Plastic Surgery

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

Company	Trade Name	510(k) Number
Cork Medical	Cork Medical Products Nisus Negative Pressure Wound Therapy System	K140022

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

Cork Medical has developed a negative pressure wound therapy pump with the same intended

use as its predicate device, Cork Medical Products Nisus Negative Pressure Wound Therapy System (K140022) but with a compacted footprint compared to the predict device.

The VERSA Negative Pressure Wound Therapy 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 (K140022) which uses multiple buttons and menus to adjust settings.

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 Pressure Wound Therapy System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004).

The VERSA Negative Pressure Wound Therapy System is not intended for home use environments.

PHYSICIAN ORDERS

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

Use of the VERSA NPWT System must be prescribed by a physician per the stated indications for use. As a condition of use, the VERSA NPWT System should only be used by qualified and authorized personnel.

The user must have the necessary knowledge of the specific medical application for which negative pressure wound therapy is being used.

Prior to placement of the VERSA NPWT System, the medical professional treating the wound must assess how to best use the system for an individual wound. It Is important to carefully assess the wound and patient to ensure clinical indications for negative pressure wound therapy are met.

USER

The VERSA Negative Pressure Wound Therapy System is a prescribed device to be used under the guidance of licensed healthcare professionals. The VERSA NPWT System Instructions for use provide information regarding safe and effective operation of the VERSA Negative Pressure Wound Therapy System.

USE ENVIRONMENT

VERSA NPWT System is designed for the following environmental conditions:

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

PREDICATE PRODUCT COMPARISON TABLE **807.92(a)(6)**

	Subject Device	**Predicate Device**
Company	Cork Medical	Cork Medical
Device Name	VERSA Negative Pressure Wound Therapy System	Cork Medical Products Nisus Negative Pressure Wound Therapy System
510(k) Number	K230677	K140022
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 Cork Medical Products Nisus 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.
Features	• Compact size • 2 continuous pressure settings of 75mm/Hg and 125 mm/Hg • Disposable batteries • Variable intermittent mode	• Multiple keys for navigation including power, menu/select, exit, up arrow, down arrow, left arrow, right arrow • Continuous Setting • Variable Intermittent
Suction Capacity	2 liters / minute	4 liters / minute
Maximum Vacuum Pressure	170 mm/Hg	220-mmHg
Power Requirements	3 x 1.5 V (3 AA battery)	18 VDC, 2A
Battery Type	Li-ion	Li-ion
Dimensions	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	151 x 108 x 71-mm (~6 x 4.3 x 2.8-inches)

Weight	0.6 lb	0.575-kg (~1.27-lb)
Reusable	Yes	Yes
Sterile	Non-sterile	Non-sterile
Compliance	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	IEC 60601-1, 3rd Edition (AAMI IES 60601-1, CAN/CSA C22.2 No. 60601-1-08, EN 60601-1) IEC 60601-1-2 IEC 60601-1-6/IEC 62366 IEC 60601-1-11
Storage & Shipping Conditions	-30ºC (-22ºF) without relative humidity control to 60ºC (140ºF) up to 90% relative humidity (non-condensing)	-25ºC (-13ºF) without relative humidity control to 44ºC (111ºF) up to 93% relative humidity (noncondensing)
Environmental Conditions	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	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	*Canisters:* One canister size 100 ml Features: hydrophobic membrane filter, liquid solidifier Bench Testing completed utilized accessories previously cleared under (K132004)	*Canisters:* One canister size 250mL Features: hydrophobic membrane filter, liquid solidifier (cleared with application) *Wound Dressing Kit: Cork NPWT Wound Dressing Kit (K132004)* Bench Testing utilized canisters in application, and accessories cleared on separate application.

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

The VERSA Negative Pressure Wound Therapy System underwent bench performance testing to establish basic functionality. The bench performance tests conducted are:

- Continuous Mode Typical Pressure (75-mmHg) Test
- Continuous Mode Typical Pressure (125-mmHg) Test
- Intermittent Mode Test
- Low Battery Test
- Leak Alarm
- Block Alarm
- Canister full
- Flow Rate Testing
- One-Year Aged Canister Testing
- Post-Storage Conditional Testing
- Battery Run-Time Testing

The testing results show the VERSA NPWT System functioned as expected. Performance tests used simulated wound exudate. Pressure measurements were taken using a wound test bed fixture.

Software Verification and Validation Testing
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern. The corresponding software documentation required for a 510(k) submission is included per "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" as published by the FDA.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the VERSA Negative Pressure Wound Therapy System. The system complies with the IEC 60601-1: 2005, IEC 60601-1-6: 2010, and IEC 60601-1-11: 2010 standards for safety and the IEC 60601-1-2: ed 4.0 (2014-02) standard for EMC.

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

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

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

Cork Medical concludes, based on nonclinical testing, that the VERSA Negative Pressure Wound Therapy System is as safe, as effective, and performs as well as the predicate device, Cork Medical Products Nisus Negative Pressure Wound Therapy System (K140022).