June 27, 2025

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

Re: K243187
Trade/Device Name: Nisus ONE Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 22, 2025
Received: May 22, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 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)*
K243187

Device Name
Nisus ONE Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
The Nisus ONE Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device allows wound management.

The Nisus ONE Negative Pressure Wound Therapy System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004)

The Nisus ONE 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
[21 CFR 807.92(c)]
Nisus ONE Negative Pressure Wound Therapy System

DATE PREPARED	26 June 2025
APPLICANT	Cork Medical 8000 Castleway Drive Indianapolis, IN 46250
REGISTRATION NUMBER	3010588638
CONTACT	Antonio Williams Regulatory Engineer Phone:317-361-4387 Email: awilliams@corkmedical.com
TRADE NAME	Nisus ONE Negative Pressure Wound Therapy System
COMMON NAME	Nisus ONE NPWT System
DEVICE CLASSIFICATION	Class II per 21 CFR 878.4780
CLASSIFICATION NAME	Powered Suction Pump
PRODUCT CODE	OMP
PANEL	General & Plastic Surgery
PREDICATE DEVICE	The Cork Medical Products Nisus Negative Pressure Wound Therapy System (K140022)

INDICATION FOR USE:
The Nisus ONE Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device allows wound management.

The Nisus ONE Negative Pressure Wound Therapy System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004)

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

DEVICE DESCRIPTION:

Cork Medical has developed a negative pressure wound therapy (NPWT) system with the same intended use as the predicate device (K140022). The subject device features a modified user interface, and an adjusted feature set intended to support ease of use, while maintaining the same fundamental therapeutic function and performance characteristics as the predicate device. The Nisus ONE Negative Pressure Wound Therapy System interface utilizes a single membrane switch keypad to power the device and switch between continuous and intermittent therapy modes.

The device display is limited to presenting critical operational parameters, including therapy mode, battery status, and target pressure settings**.** Visual and audible alarms are consistent with the predicate device (K140022) and alert critical battery, pressure leakage, system blockage, and full canister occur. While the Nisus ONE NPWT System's interface differentiates from the predicate Cork NPWT system, the mechanical components and therapy application

are identical. The new model is intended to enhance accessibility by aligning with the needs of a broad and diverse patient population across various care settings.

The components included within the Nisus ONE NPWT System are:

- Nisus ONE Negative Pressure Wound Therapy Pump (OCMPP-100)
- Nisus ONE Pump Battery Charger (NIS-CHRG-A-18)
- Nisus NPWT Canister 500-mL (CPC-500)
- Nisus NPWT Canister 250-mL (CPC-250, previously cleared in K140022)

Accessory components are required to operate the device. Injection molded components are sonically welded to form a canister designed to mate with the pump and collect excess exudates, infectious material, and tissue debris. The Nisus NPWT Canister 250-mL design was previously cleared in the Nisus NPWT system 510k application (K140022). The Nisus NPWT Canister 500-mL is based on the same design as the Nisus NPWT Canister 250-mL. The dimensions were enlarged to provide a larger reservoir for patient convenience. Thus, the subject and predicate canisters have substantially equivalent characteristics.

The Wound Kit comes in multiple iterations containing a minimum of one port pad, wound foam and peel and stick drape. Integrated with the pump mechanism, these components ensure the safe and efficient removal of wound exudate. NPWT Accessories were previously cleared in K132004. Our application for the Nisus ONE NPWT system includes no revisions to these previously cleared components.

DEVICE COMPARISON – SUMMARY

A comparison table evaluating the subject device, and the predicate device is on the following page. The Nisus ONE NPWT System design is an iteration of the existing Cork NPWT System with the key difference being the patient interface. The Nisus ONE Negative Pressure Wound Therapy System contains fewer features and defaults to the most common therapy mode and pressure: Continuous at 125mmHg; however, the Nisus One NPWT System uses only one button on the pump to manipulate settings.

The Nisus ONE NPWT System and the predicate Cork NPWT System have the same indication for use and technical data differing only on dimensions, weight, suction capacity, storage and shipping conditions and usage of a 500ml canister.

- ***Dimensions / Weight***
  Dimensions: 6” (H) x 4.6” (W) x 3.3” (D) Weight: 2 lbs. with canister

- ***500 ml canister***
  Dimensions: 5.85” (H) x 4.65” (W) x 3.72” (D) Weight: 4oz

- ***Suction capacity of ~7 lpm***

- ***Storage & Shipping Conditions***
  -5ºC (23ºF) without relative humidity control to 35ºC (95ºF) up to 75% relative humidity (non-condensing)

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technical differences between the Nisus ONE NPWT System and predicates include the membrane switch, user interface (UI), and USB port. The membrane switch on the Nisus ONE NPWT System has been modified from that of the predicate in having a singular button for user control of the device. The UI has been simplified as well to a single screen that shows what operation mode the Nisus ONE NPWT System is currently in. Finally, the USB port has been internalized to the Nisus ONE NPWT System and is not accessible.

COMPARISON WITH PREDICATE DEVICE:

	Subject Device	**Predicate Device**
Company	Cork Medical	Cork Medical Products
Device Name	Nisus One Negative Pressure Wound Therapy System	Nisus Negative Pressure Wound Therapy System
510(k) Number	K243187	K140022
Regulation Number / Product Code	21 CFR 878.4780 / OMP	21 CFR 878.4780 / OMP
Indications for Use	The Nisus ONE Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device allows wound management. The Nisus ONE Negative Pressure Wound Therapy System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004) The Nisus ONE Negative Pressure Wound Therapy System is suitable for use in both a professional healthcare facility and home use environment.	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	• One button navigation. • Automatically set up to deliver the most common therapy mode (continuous at 125mmHg) • Variable Intermittent Mode (high pressure: 125-mmHg, low pressure: 40-mmHg)	• Equipped with a multi-function keypad, including discrete controls for Power, Menu/Select, Exit, and four-way directional navigation (Up, Down, Left, Right) • Continuous Mode (40-mmHg – 200-mmHg) at increments of 5ml of mmHg • Variable Intermittent Mode (high pressure: 125-mmHg, low pressure: 40-mmHg)
Pump – Technical Data		

Suction Capacity	7 liters / minute	4 liters / minute
Maximum Vacuum Pressure	220-mmHg (Upon Canister Full Alarm Only)	220-mmHg (Upon Canister Full Alarm Only)
Power Requirements	18 VDC, 2A	18 VDC, 2A
Battery Type	Li-ion	Li-ion
Dimensions	151 x 117 x 84-mm (~6 x 4.6 x 3.3-inches)	151 x 108 x 71-mm (~6 x 4.3 x 2.8-inches)
Weight	0.616-kg (~1.36-lb)	0.575-kg (~1.27-lb)
Reusable	Yes	Yes
Sterile	Non-sterile	Non-sterile

Compliance	IEC 60601-1, 4th Edition (AAMI ES 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	IEC 60601-1, 3rd Edition (AAMI ES 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	-5ºC (23ºF) without relative humidity control to 35ºC (95ºF) up to 75% relative humidity (non-condensing)	-25ºC (-13ºF) without relative humidity control to 44ºC (111ºF) up to 93% relative humidity (non-condensing)
Environmental Conditions	Operating Temperature: 18ºC to 34ºC (65ºF to 94ºF) Operating Relative Humidity: 10% - 95% non-condensing 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	Two Sizes: 250mL, 500mL Features: hydrophobic membrane filter, liquid solidifier (250mL cleared on K140022)	One Size: 250mL Features: hydrophobic membrane filter, liquid solidifier (cleared with application)
Wound Dressing Kit	Wound Foam: Reticulated polyether based polyurethane foam (A30M) Wound Drape: Transparent polyurethane film with adhesive backing Port Pad Assembly: Silicone port pad, Port Pad Skirt (Transparent polyurethane film with adhesive backing), Drainage tubing, Luer connector, Pinch Clamp Previously cleared in K132004 Provided sterile	Wound Foam: Reticulated polyether based polyurethane foam (A30M) Wound Drape: Transparent polyurethane film with adhesive backing Port Pad Assembly: Silicone port pad, Port Pad Skirt (Transparent polyurethane film with adhesive backing), Drainage tubing, Luer connector, Pinch Clamp Previously cleared in K132004 Provided sterile

NONCLINICAL TESTS

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

- Continuous Mode (125-mmHg) Test
- Variable Intermittent Mode ((high pressure: 125-mmHg, low pressure: 40-mmHg) Test

- Low Battery Test
- Leak Alarm Testing
- Block Alarm Testing
- Canister Full Alarm Testing
- Non-aged canister testing on the 250 ml & 500 ml Canisters
- Aged canister testing on the 250 ml & 500 ml Canisters
- Flow rate testing of the Nisus ONE NPWT Pump
- Functional Post Storage Environmental Testing

The testing results show the Nisus One 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."

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Nisus One 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.

Additional Non-Clinical Testing Conducted

IEC 62366:2007 - Medical devices - Application of usability engineering to medical devices.

USABILITY TESTING/HUMAN FACTORS TESTING

Useability/Human Factors Testing was performed to confirm that the intended user group was found to meet expected use goals.

CLININCAL TEST

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

CONCLUSION:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Cork Medical concludes that the Nisus One Negative Pressure Wound Therapy System is as safe and effective as the predicate device, Cork Medical Products Nisus Negative Pressure wound Therapy System (K140022).