May 21, 2026

Cork Medical
Antonio Williams
Regulatory Engineer
8000 Castleway Dr.
Indianapolis, Indiana 46112

Re: K261291
Trade/Device Name: Cork Medical Products Nisus Negative Pressure Wound Therapy System and Nisus Touch Negative Pressure Wound Therapy Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: April 19, 2026
Received: April 20, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261291

Device Name
Cork Medical Products Nisus Negative Pressure Wound Therapy System and Nisus Touch Negative Pressure Wound Therapy Pump

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

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

The systems consist of a negative pressure wound therapy unit, dressings, tubing, and disposable canisters, including available canister configurations up to 500 mL capacity.

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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510(k) Summary
[as required by 21 CFR 807.92(c)]

DATE PREPARED	31 March 2026
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	Cork Medical Products Nisus Negative Pressure Wound Therapy System and Nisus Touch Negative Pressure Wound Therapy Pump
COMMON NAME	Cork NPWT System and Nisus Touch Negative Pressure Wound Therapy Pump
MODEL NUMBER	CMPP-100 and TCMPP-100
REGULATORY NUMBER	Class II
DEVICE CLASSIFICATION	21 CFR 878.4780
CLASSIFICATION NAME	Powered Suction Pump
PRODUCT CODE	OMP
PANEL	General & Plastic Surgery
PREDICATE DEVICE	Nisus ONE Negative Pressure Wound Therapy System (K243187)

DEVICE DESCRIPTION:
The Nisus NPWT Canister 500-mL (CPC-500) is a disposable canister intended for use with negative pressure wound therapy (NPWT) systems for the collection of wound exudate. The canister mechanically interfaces with compatible NPWT pump systems and connects to wound dressings via standard tubing and connectors.

The device is provided as a single-use, non-sterile product and is packaged in a flexible packaging system.

The Nisus NPWT Canister 500-mL (CPC-500) has the same intended use, fundamental scientific technology, and performance characteristics as the legally marketed predicate device. The device differs only in canister volume and minor dimensional attributes necessary to achieve the 500-mL capacity. These differences do not affect the safety or effectiveness of the device.

The materials of construction and method of operation are equivalent to those of the predicate device.

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

The Cork NPWT System and Nisus Touch NPWT System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004)

The systems consist of a negative pressure wound therapy unit, dressings, tubing, and disposable canisters, including available canister configurations up to 500-mL capacity.

DECSRIPTION OF THE MODIFICATION

This Special 510(k) is being submitted to add a new 500-mL disposable canister compatible with the Cork NPWT System and Nisus Touch Negative Pressure Wound Therapy Pump. The modification does not affect the device's indications for use, operating principles, or energy delivery. The canister functions identically to existing cleared canisters, differing only in volume capacity and minor dimensional attributes.

COMPARISON WITH PREDICATE DEVICE:

The subject devices is identical to the predicate device with respect to design, materials of construction, technological characteristics, performance, safety features, and intended use. The only difference is updated labeling identifying the Cork NPWT System and Nisus Touch Negative Pressure Wound Therapy Pump. The Nisus NPWT Canister 500-mL (CPC-500) remain unchanged from the legally marketed predicate device.

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(5)]			
Characteristic	**Predicate Device** **Nisus One (K243187)**	**Subject Device(s)** **Cork NPWT System/Nisus Touch NPWT Pump**	**Comparison**
Manufacturer	Cork Medical	Cork Medical	Same
Device Type	NPWT System with compatible fluid canister	NPWT Systems with the same compatible fluid canister	Equivalent (same functional family)
Trade Name	Nisus One (K243187)	Cork NPWT System (K140022) Nisus Touch Negative Pressure Wound Therapy Pump (K203693)	Equivalent (same functional family)
Regulatory Classification	Class II, Product Code: OMP (Negative Pressure Wound Therapy)	Same	Same
Intended Use	The canister is intended to collect wound exudate during NPWT therapy when used in conjunction with the Nisus NPWT System.	Identical intended use	Same
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	Cork NPWT System and Nisus Touch Negative Pressure Wound Therapy Pump is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device allows wound management. The Cork NPWT System and Nisus Touch Negative Pressure Wound Therapy Pump is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004)	Equivalent

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(5)]			
Characteristic	**Predicate Device Nisus One (K243187)**	**Subject Device(s) Cork NPWT System/Nisus Touch NPWT Pump**	**Comparison**
	and home use environment.	The systems consist of a negative pressure wound therapy unit, dressings, tubing, and disposable canisters, including available canister configurations up to 500-mL capacity.	
Compatibility	Nisus One NPWT System	Cork NPWT System and Nisus Touch Negative Pressure Wound Therapy Pump	Equivalent (verified)
Technological Characteristics	Electric vacuum pump delivering controlled negative pressure	Same operating principle, pump technology, and control methods	Same
Use of Canister	Uses a passive, non-powered canister for fluid collection	Uses the same passive canister with no modifications	Same
Operating Principle	Disposable single use 500-mL canister designed for use in conjunction with a sterile dressing system and a therapy unit	Same	Identical
Mechanical Interface with Canister	Defined connector geometry and latch system	Same geometric interface; validated for equivalence	Equivalent
Materials (Canister)	Medical-grade polymer canister housing, seals, hydrophobic filter	Same	Identical
Electrical Components	Powered pump; canister non-electrical	Powered pump; canister non-electrical	Same
Thermal Characteristics	No heat generation from canister; pump meets IEC 60601-1 electrical safety (applicable under original clearance)	Same; canister introduces no thermal risk	Same
Performance	Vacuum integrity and leak resistance established	Verification testing confirms equivalence	Equivalent
Biocompatibility (Canister)	The canister does not have direct or indirect patient contact	Same	Same
Sterility	Non-Sterile	Same	Same
Shelf Life	Validated for canister and packaging	Same shelf life; no changes to packaging or materials	Same
Clinical Performance	Supported by prior NPWT system data	Same intended use and performance expectations	Same
Risk Profile	Acceptable per prior clearance	Risk unchanged; no new hazards	Same
Conclusion	Legally marketed NPWT system and canister	Performs equivalently with identical canister; no new safety or performance concerns	Substantially Equivalent

NONCLINICAL TESTS

The Nisus NPWT Canister 500-mL (CPC-500) underwent bench verification testing to confirm basic functionality and performance when used with the Cork NPWT System and Nisus Touch Negative Pressure Wound Therapy Pump. Testing was conducted using simulated wound exudate under representative operating conditions.

The following bench performance testing were performed:

- Leak Alarm Testing
- Block Alarm Testing
- Canister Full Alarm Testing
- 3-Day Functionality Testing
- Low Continuous Mode 40 mm-hg Testing
- High Continuous Mode 200 mm-hg Testing
- Flow rate with simulated exudate Testing
- Battery Runtime with simulated exudate Testing

Test results demonstrated that the Nisus NPWT Canister 500-mL (CPC-500) functioned as intended and met predefined acceptance criteria when used with both the Cork NPWT System and Nisus Touch Negative Pressure Wound Therapy Pump. No performance anomalies were observed during testing, and device functionality was consistent across all evaluated test conditions.

CONCLUSION:

Based on the identical intended use, similar technological characteristics, and successful verification and validation testing, the Cork NPWT System and Nisus Touch Negative Pressure Wound Therapy Pump is substantially equivalent to the predicate device. The addition of the Nisus NPWT Canister 500-mL (CPC-500) does not raise new questions of safety or effectiveness.