August 13, 2021

Cork Medical Products, LLC
Patrick McGinley
Chief Executive Officer
8000 Castleway Drive
Indianapolis, Indiana 46250

Re: K203693
Trade/Device Name: 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: June 16, 2021
Received: June 21, 2021

Dear Patrick McGinley:

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 and Part 809); 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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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)*
K203693

Device Name
Nisus Touch Negative Pressure Wound Therapy Pump

Indications for Use *(Describe)*
The 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 may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.

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

807.92(c)

SPONSOR 807.92(a)(1)

Company Name: Cork Medical Products LLC
Company Address: 8000 Castleway Drive
Indianapolis, IN 46250

Telephone: 866-551-2580
Fax: 844-269-8439
Contact Person: Patrick McGinley

Date Prepared: August 6th, 2021

DEVICE NAME 807.92(a)(2)

Trade Name: Nisus Touch Negative Pressure Wound Therapy Pump
System Common/Usual Name: Negative Pressure Wound Therapy Powered Suction Pump
Classification Name: Powered Suction Pump

Regulation Number: 21 CFR 878.4780
Product Code: OMP
Device Class: Class II

PREDICATE DEVICE 807.92(a)(3)

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

DEVICE DESCRIPTION 807.92(a)(4)

Cork Medical Products has developed a negative pressure wound therapy pump with the same intended use as its predicate device (K140022) but has the addition of an integrated touch screen. The Nisus Touch and Nisus pumps are nearly identical in appearance and utilize the same buttons to power the device and adjust pump settings; however, the Nisus Touch offers the alternative touch screen to easily maneuver between settings based on operator preference. Visual and audible alarms are consistent with the predicate device K140022 and alert the user when critical battery, pressure leakage, system blockage, and full canister occurs. Additionally, the Nisus Touch mechanical components and therapy application are identical to the Nisus pump. The intent of the new model is to appeal to users who encounter touch screens in daily technology and might feel navigation by touch screen is more simplistic.

The components included within the Cork Nisus Touch NPWT Pump are:

- Nisus Touch Negative Pressure Wound Therapy Pump
- Nisus Touch Pump Battery Charger

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 canister design was previously provided clearance within the Nisus NPWT system 510k application (K140022).

The Wound Kit comes in multiple iterations containing a minimum of one port pad, wound foam and peel and stick drape. These components are used in conjunction with the pump to ensure safe transfer of the wound debris to the canister. The NPWT Accessories were previously provided clearance on K132004. Our application for the Nisus Touch NPWT system includes no revisions to these previously cleared components.

DEVICE INTENDED USE 807.92(a)(5)

Indications for Use

The 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 may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.

Physician Orders

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

Use of the Nisus Touch NPWT Pump must be prescribed by a physician per the stated indications for use. As a condition of use, the Nisus Touch NPWT Pump 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 Nisus Touch NPWT Pump, 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 Nisus Touch NPWT Pump is designed for use by licensed healthcare professionals only. The keypad and device menus are locked by the healthcare professional to prevent patient from changing the setting prescribed by the physician.

NOTE: Patient functions are limited to power on/off and respond to any alarm conditions.

Use Environment

Cork Medical Products Nisus Touch NPWT Pump 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 Products	Cork Medical Products
Device Name	Nisus Touch Negative Pressure Wound Therapy Pump	Nisus Negative Pressure Wound Therapy System
510(k) Number	K203693	K140022
Regulation Number / Product Code	21 CFR 878.4780 / OMP	21 CFR 878.4780 / OMP
Indications for Use	The 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 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	• Multiple keys for navigation including: power, menu/select, exit, up arrow, down arrow, left arrow, right arrow • Touch screen capability to maneuver between therapy modes and device settings	• Multiple keys for navigation including: power, menu/select, exit, up arrow, down arrow, left arrow, right arrow
Suction Capacity	~8-10 liters / minute	4 liters / minute
Maximum Vacuum Pressure	200-mmHg	220-mmHg
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	-25ºC (-13ºF) without relative humidity control to 70ºC (158ºF) up to 93% relative humidity (non-condensing)	-25ºC (-13ºF) without relative humidity control to 70ºC (158ºF) up to 93% relative humidity (non-condensing)
Environmental Conditions	Operating Temperature: 18ºC - 34ºC (65ºF - 94ºF) Operating Relative Humidity: 10% - 95% non-condensing Operating Pressure: 700-hPA – 1060-hPA (10.15-atm – 15.37-atm) atmospheric pressure	Operating Temperature: 5ºC - 40ºC (41ºF - 104ºF) Operating Relative Humidity: 15% - 93% non-condensing 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 (cleared on K14022) *Wound Dressing Kit:* Wound Foam Wound Drape Port Pad Assembly Previously cleared on K132004 Provided sterile Bench Testing completed utilized accessories previously cleared on separate 510k applications to mimic the predicate device setting.	*Canisters:* Two Sizes: 250mL, 500mL Features: hydrophobic membrane filter, liquid solidifier (cleared with application) *Wound Dressing Kit:* Wound Foam Wound Drape Port Pad Assembly Previously cleared on K132004 Provided sterile Bench Testing utilized canisters in application, and accessories cleared on separate application.

NONCLINICAL TESTS 807.92(b)(1)

The Cork Medical Products Nisus Touch Negative Pressure Wound Therapy Pump underwent bench performance testing to establish basic functionality. The bench performance tests conducted are:

- Continuous Mode Low Pressure (40-mmHg) Test
- Continuous Mode Typical Pressure (125-mmHg) Test
- Continuous Mode High Pressure (200-mmHg) Test
- Intermittent Mode Test
- Low Battery Test
- Leakage Alarm Test
- Blockage Alarm Test
- Canister Full Alarm Test
- Suction Capacity and Maximum Vacuum Pressures

The testing results show the Nisus Touch NPWT pump 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 Nisus Touch Negative Pressure Wound Therapy Pump. 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.

CLINICAL TESTS 807.92(b)(2)

No clinical testing required to support this 510(k) submission. No clinical testing has been performed.

CONCLUSIONS 807.92(b)(3)

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