March 28, 2019

KCI USA, Inc.
Melanie Avila
Senior Manager, Regulatory Affairs
6203 Farinon Drive
San Antonio, Texas 78249

Re: K181505
Trade/Device Name: V.A.C. DERMATAC™ Drape
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: February 20, 2019
Received: February 21, 2019

Dear Melanie Avila:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kimberly Ferlin -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181505

Device Name
V.A.C. DERMATAC Drape

Indications for Use *(Describe)*
The V.A.C. DERMATAC™ Drape is an accessory to the:

• ACTIV.A.C.™, INFOV.A.C.™, V.A.C. SIMPLICITY™, V.A.C.VIA™ and V.A.C. FREEDOM™ Negative Pressure Wound Therapy Systems, which are integrated wound management systems for use in acute, extended and home care settings.

• V.A.C.ULTA™ and V.A.C.RX4™ Negative Pressure Wound Therapy Systems, which are integrated wound management systems for use in acute care settings and other professional healthcare environments where product use is conducted by or under the supervision of a qualified healthcare professional.

When used on open wounds, they are intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

When used on closed surgical incisions, they are intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

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

V.A.C. DERMATAC Drape

Submitter

KCI USA, Inc.

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San Antonio, TX 78249

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Contact Person: Melanie Avila

Date Prepared: March 28, 2019

Name of Device: V.A.C. DERMATAC™ Drape

Common or Usual Name: Negative Pressure Wound Therapy System

Classification Name: Negative Pressure Wound Therapy Powered Suction Pump (and components)

Regulatory Class: 878.4780

Product Code: OMP

Predicate Device: V.A.C. Negative Pressure Wound Therapy Dressing System, cleared under 510(k) K133276

Device Description: The V.A.C. DERMATAC Drape is a semi-occlusive wound drape that is used as an accessory to the V.A.C. Therapy System. The V.A.C. DERMATAC Drape is single-use and it is provided sterile. The V.A.C DERMATAC Drape provides a sealed environment which allows for a moist wound environment and it allows for the delivery and maintenance of negative pressure at the wound site.

The drape consists of a polyurethane film with acrylic adhesive with a perforated silicone layer. The perforations in the silicone layer expose the acrylic adhesive coated on the polyurethane film. The

acrylic adhesive secures the drape to the periwound and the silicone layer primarily provides a seal for negative pressure.

The V.A.C. Therapy System is comprised of the following:

- Software controlled negative pressure therapy unit
- Disposable canister which collects wound exudate
- Polyurethane foam dressing
- Semi-occlusive wound drape

Indications for Use

The V.A.C. DERMATAC™ Drape is an accessory to the:

• ACTIV.A.C.™, INFOV.A.C.™, V.A.C. SIMPLICITY™, V.A.C.VIA™ and V.A.C. FREEDOM™ Negative Pressure Wound Therapy Systems, which are integrated wound management systems for use in acute, extended and home care settings.

• V.A.C.ULTA™ and V.A.C.RX4™ Negative Pressure Wound Therapy Systems, which are integrated wound management systems for use in acute care settings and other professional healthcare environments where product use is conducted by or under the supervision of a qualified healthcare professional.

When used on open wounds, they are intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

When used on closed surgical incisions, they are intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]			
Characteristic	**Subject Device: V.A.C. DERMATAC Drape K181505**	**Predicate Device: V.A.C. NPWT Dressing System, cleared under K133276**	**Reference Devices:** • **ACTIVAC Therapy Unit (K063692)** • **INFOVAC Therapy Unit (K063740)** • **V.A.C. SIMPLICITY (K111280)** • **V.A.C. FREEDOM (K032310)** • **V.A.C.VIA (K173447)** • **V.A.C.ULTA (K162790)** • **V.A.C.RX4 (K160487)**
Intended Use	Same as predicate	To provide a sealed environment, which allows for the delivery and maintenance of negative pressure at the wound site as well as protecting the wound site from external contamination.	Same as predicate
Indicated Wound Types	Same as predicate	• Chronic • Acute • Traumatic • Subacute • Dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic, pressure or venous insufficiency) • Flaps and grafts • Surgically closed incisions	Same as predicate
Dressing system components	Same as predicate	• Drape with adhesive • Sensing pad and tubing • Foam dressing	Same as predicate
Care Setting	Same as predicate	The V.A.C. NPWT Dressing System can be used both in the Acute and Post-Acute setting.	Same as predicate
Shelf life	1 year	3 years	N/A

Summary of Technological Characteristics

At a high level, the subject and predicate devices are based on the following same technological elements.

Performance Data

Summary of non-clinical tests conducted for determination of substantial equivalence

- Testing to confirm DERMATAC Drape is biocompatible:
  - ISO 10993-1. (2009). Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
  - ISO 10993-10. (2010). Biological evaluation of medical devices –Part 10: Tests for irritation and skin sensitization.
  - ISO 10993-11. (2006). Biological evaluation of medical devices – Part 11: Tests for systemic toxicity.
  - ISO 10993-12. (2012). Biological evaluation of medical devices – Part 12: Sample preparation and reference materials.
  - ISO 10993-17. (2002). Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances.
  - ISO 10993-18. (2005). Biological evaluation of medical devices – Part 18: Chemical characterization of materials.
  - ISO 10993-3. (2014). Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
  - ISO 10993-5. (2009). Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- **Shelf Life** - package integrity testing of DERMATAC Drape sterile barrier packaging following 3 cycles of EtO sterilization and ship distribution of product accelerated aged to an equivalent real time of 2 year (T=2yr AA) was conducted using seal strength and bubble emission methods. The drape met all requirements.
- **Adhesive Peel Test –** drape was adhered to stainless steel plate and the force required to remove the drape was measured. The results documented demonstrate that DERMATAC Drape meets specification requirements.
- **Moisture Vapor Transmission Rate Test** - drape met minimum requirements when using the ASTM E96/E96M Upright Cup Method at 38°C and 10%RH for MVTR.
- **Negative Pressure Maintenance System Test** - negative pressure performance testing was conducted using simulated wound exudate, maximum air leak rate, worst case dressing configuration and for the maximum use life of the dressings. The negative pressure performance test also included re-application cycling to demonstrate that the drape is capable of being applied, lifted and re-applied. The results documented that DERMATAC Drape is capable of maintaining negative pressure within specification.
- **Peel Adhesion with Re-Application Cycling Testing –** drape was applied, removed and then re-applied multiple times and then subjected to peel force

evaluation. Results demonstrated that the drape was capable of meeting specification for peel adhesion after multiple re-application and removals.

In all instances, V.A.C. DERMATAC Drape functioned as intended and all test results observed were as expected.

No clinical tests were necessary, however human factors engineering assessment with 30 representative users indicated that the new user interface could be safely and effectively used by all test subjects.

Conclusions

The V.A.C. DERMATAC Drape is as safe and effective as the V.A.C. NPWT Dressing System. The V.A.C. DERMATAC Drape has the same intended uses and similar indications, and technological characteristics as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. Performance data demonstrate that the V.A.C. DERMATAC Drape is as safe and effective as the V.A.C. Negative Pressure Wound Therapy (NPWT) Dressing System. Thus, the V.A.C. DERMATAC Drape is substantially equivalent.