May 18, 2020

KCI USA, Inc
Margaret Marsh
Regulatory Affairs Advanced Specialist
6203 Farinon Drive
San Antonio, Texas 78249

Re: K200390
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 17, 2020
Received: February 18, 2020

Dear Margaret Marsh:

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/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,

Anjana Jain
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200390

Device Name
V.A.C. DERMATAC™ Drape

Indications for Use *(Describe)*
The V.A.C. DERMATAC™ Drape is an accessory to the following V.A.C.® Therapy Negative Pressure Wound Therapy Systems:
• ACTIV.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™ , INFOV.A.C.™ 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, these systems are intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention, 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.

The V.A.C. DERMATAC™ Drape is also an accessory to the V.A.C. VERAFLO Therapy (Instillation) provided by the V.A.C.ULTA™ Therapy Unit.

V.A.C. VERAFLO™ Therapy is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

V.A.C. VERAFLO™ Therapy is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.

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
V.A.C. DERMATAC™ Drape

Submitter Information [21 CFR 807.92(a)(1)]	
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive San Antonio, TX 78249
Phone number	210 255-6481
Fax number	210-255-6727
Establishment Registration Number	3005178245
Name of contact person	Margaret Marsh
Date prepared	May 18, 2020
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	V.A.C. DERMATAC™ Drape
Common or usual name	Negative Pressure Wound Therapy System component
Classification name	Negative Pressure Wound Therapy Powered Suction Pump (and components)
Classification panel	General and Plastic Surgery
Regulation	878.4780
Product Code(s)	OMP
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	V.A.C. DERMATAC™ Drape, cleared under 510(k) K181505.
Device description [21 CFR 807.92(a)(4)]	The V.A.C. DERMATAC™ Drape is a semi-occlusive wound drape that is used as an accessory to the V.A.C.® Therapy and V.A.C. VERAFLO™ Therapy Systems. The V.A.C. DERMATAC™ Drape is a single-use, sterile covering that provides a sealed environment for delivery of these therapies. It also allows for a moist wound environment. 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 skin, thus creating a sealed wound environment. The therapy systems with which it is used are comprised of the following: • Software controlled therapy unit that provides negative pressure and, in the case of V.A.C. VERAFLO™ Therapy, a pump for controlled delivery of topical wound solutions. • Disposable canister which collects wound exudate and, in the case of V.A.C. VERAFLO™ Therapy, instilled solutions • Foam dressing for placement into the wound • Semi-occlusive drape that covers the dressing • Tubing set that connects the dressing to the therapy unit.

510(k) SUMMARY
V.A.C. DERMATAC™ Drape

Indications for use [21 CFR 807.92(a)(5)]	The V.A.C. DERMATAC™ Drape is an accessory to the following V.A.C.® Therapy Negative Pressure Wound Therapy Systems: • ACTIV.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. • The V.A.C.ULTA™, INFOV.A.C™. and V.A.C.RX4™ Negative Pressure Wound Therapy Systems 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, these systems 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. The V.A.C. DERMATAC™ Drape is also an accessory to the V.A.C. VERAFLO™ Therapy (Instillation) provided by the V.A.C.ULTA™ Therapy Unit. V.A.C. VERAFLO™ Therapy is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed. V.A.C. VERAFLO™ Therapy is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.
Comparison of the Technological Characteristics (i.e., design, material, chemical composition, energy source) with the Predicate Device [21 CFR 807.92(a)(6)]	
There is no difference between the subject and predicate drapes in terms of materials of construction, packaging, sterilization, method of application, indicated wound types, as well as use with the V.A.C.® Negative Pressure Wound Therapy provided by the V.A.C.ULTA™, ACTIV.A.C.™, V.A.C. SIMPLICITY™, V.A.C.VIA™, V.A.C. FREEDOM™, INFOV.A.C™, and V.A.C.RX4™ Therapy Units. The only significant difference between the subject and predicate drapes is in the intended use, which has been expanded to include use with the V.A.C. VERAFLO™ Therapy, also provided by the V.A.C.ULTA™ Therapy Unit.	

510(k) SUMMARY
V.A.C. DERMATAC™ Drape

Performance Data [21 CFR 807.92(b)]
Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]
• 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 results documented that the V.A.C. DERMATAC Drape™ is capable of maintaining negative pressure within specification.
Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]
No clinical tests were required for a demonstration of substantial equivalence. However, a usability assessment was conducted.
Conclusions drawn [21 CFR 807.92(b)(3)]
Tthe subject device is substantially equivalent to the predicate device with respect to indications, and technological characteristics. There are no new questions regarding safety or effectiveness.