DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 20, 2016

Kci Usa, Inc. (kinetic Concepts, Inc.)
% Melanie Avila
Senior Manager, Regulatory Affairs
Kci Usa, Inc.
6203 Farinon Drive
San Antonio, Texas 78249

Re: K160451
Trade/Device Name: V. A.c. Veraflo Cleanse Choice Dressing System For Use With The V.a.c. Ulta ...
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: February 16, 2016
Received: February 18, 2016

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160451

Device Name
V. A.C. VeraFlo Cleanse Choice Dressing System for use with the V.A.C. Ulta Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
The V.A.C. Ulta Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy with an instillation option.

Negative Pressure Wound Therapy in the absence of instillation is 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.

The instillation option 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.

The V.A.C. Ulta Negative Pressure Wound Therapy System with and without instillation 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.

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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for the V.A.C. VeraFlo Cleanse Choice Dressing System is provided below.

1. SUBMITTER

KCI USA, Inc.
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Date Prepared: February 16, 2016

2. DEVICE

Name of Device: V.A.C. VeraFlo Cleanse Choice Dressing System for use with the V.A.C. Ulta Negative Pressure Wound Therapy (NPWT) System
Common Name: Negative Pressure Wound Therapy Powered Suction Pump
Classification Regulation: 21 CFR 878.4780
Regulatory Class: II
Product Code: OMP
Panel: General and Plastic Surgery

3. PREDICATE DEVICE

Predicate Device: VeraFlo Cleanse Dressing System (K103156)

4. DEVICE DESCRIPTION

The V.A.C. VeraFlo Cleanse Choice Dressing System is intended for use with the V.A.C. Ulta Negative Pressure Wound Therapy System to deliver negative pressure wound therapy (NPWT) as well as facilitate the instillation of fluid to the wound.

The V.A.C. VeraFlo Cleanse Choice Dressing System has the same basic components as the predicate V.A.C. VeraFlo Cleanse Dressing cleared under K103156. The only difference between the two systems is the configuration of the dressing.

The subject system has a dressing that is designed with 3 separate layers. The predicate dressing, on the other hand, is a single spiral shaped rod configuration. The materials of the dressing are the same.

5. INDICATIONS FOR USE

The V.A.C. VeraFlo Cleanse Choice Dressing System is intended to be used with the V.A.C. Ulta Negative Pressure Wound Therapy System. The indications for use as follows:

> The V.A.C. Ulta Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy with an instillation option.
>
> Negative Pressure Wound Therapy in the absence of instillation is 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.
>
> The instillation option 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.
>
> The V.A.C. Ulta Negative Pressure Wound Therapy System with and without instillation 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.

Both the subject system and the predicate system are intended for use with the V.A.C. Ulta Negative Pressure Wound Therapy System. Both systems have the ability to deliver topical wound solutions and suspensions in the wound bed as well as delivery of negative pressure wound therapy. There is no change to the indications for use.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

6.1. Similarities

The V.A.C VeraFlo Cleanse Choice Dressing System is nearly identical to that of the predicate V.A.C VeraFlo Cleanse Dressing System (cleared under K103156). Both systems have the same materials, sterilization, and packaging.

The subject V.A.C. VeraFlo Cleanse Choice Dressing System has the same basic components as the predicate V.A.C. VeraFlo Cleanse Dressing System cleared under K103156. Both dressings of these systems are made from the identical open cell, reticulated, grey polyurethane ester foam stock material.

6.2. Differences

The only difference between the proposed and the predicate system is the configuration of the dressing component. The subject system has a dressing that is provided in three separate layers in an oval shape to allow for flexibility in treating wounds of various depths. The predicate dressing is a tubular shaped rod and is split along the longitudinal axis by the user for ease of configuring.

For convenience purposes, the table below compares the subject and predicate systems.

	Proposed Device	**Predicate Device**
510(k) Number	K160451	K103156
Applicant	Same as predicate	KCI USA, Inc.
Trade name	V. A.C. VeraFlo Cleanse Choice Dressing System for use with the V.A.C. Ulta Negative Pressure Wound Therapy System	V. A.C. VeraFlo Cleanse Dressing System for use with the V.A.C. Ulta Negative Pressure Wound Therapy System
Classification Regulation	Same as predicate	878.4780
Product Code	Same as predicate	OMP
Indications for Use	Same as predicate	The V.A.C.Ulta Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy with an instillation option. The V.A.C.Ulta Negative Pressure Wound Therapy System in the absence of instillation is 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. The instillation option 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. The V.A.C.Ulta Negative Pressure Wound Therapy System with and without instillation 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.
Dressing System Components	Same as predicate	V.A.C. VeraT.R.A.C. Pad Assembly
	V.A.C. VeraFlo Cleanse Choice Dressing has 3 layer design	V.A.C. VeraFlo Cleanse Dressing has a tubular shaped rod design
	Same as predicate	V.A.C. Ruler
	Same as predicate	3M ™ Cavilon™ Skin Prep
	Same as predicate	V.A.C. Advanced Drape
NPWT Therapy System Design	Same as predicate	The VeraFlo Cleanse Dressing System is intended for use with the V.A.C. Ulta NPWT system. The NPWT system consists of: • Software controlled therapy unit • Canister

	Proposed Device	**Predicate Device**
		• Negative pressure tubing and sensing pad • Instillation tubing and pad • Foam wound dressing and polyurethane occlusive drape
NPWT System Operating Principle	Same as predicate	The V.A.C. Ulta NPWT system delivers software controlled negative pressure to the wound site. The open cells of the foam dressing to which the therapy unit is connected enable distribution of the negative pressure across the surface of the wound, while the tubing transfers accumulated fluids to the canister. The NPWT system also provides automated delivery of instillation fluids into the wound bed between negative pressure therapy cycles.
Materials	Skin contact material: Same as predicate	Skin contact material: Occlusive drape (polyurethane film with acrylic adhesive)
	Wound contact material: Same as predicate	Wound contact material: Polyurethane ester foam
	Same as predicate	0.1% w/v carbon black colorant
	Same as predicate	Density in lb/ft3: 5.1 - 6.3
Performance Testing	Same as predicate	Verification testing was performed to confirm: • mechanical properties (tensile testing) • the dressing, as part of the V.A.C. Ulta Negative Pressure Wound Therapy System, delivers negative pressure • the dressing distributes instillation solution throughout the wound surface
Mechanical Properties (Tensile Strength)	Pass	≥230kPa
Sterilization	Same as predicate	Gamma Irradiation to SAL of 10^{-6}
Sterile Packaging	Same as predicate	Thermoformed tray of PETG with a Tyvek lid
Shelf life	Same as predicate	2 years

7. PERFORMANCE DATA

Bench Verification testing was performed to confirm:

- mechanical properties (tensile testing)
- the dressing, as part of the V.A.C. Ulta Negative Pressure Wound Therapy System creates negative pressure within the sealed wound bed
- the dressing distributes instillation solution throughout the wound surface

8. CONCLUSIONS

The only difference between the proposed and the predicate dressing systems is the configuration of the dressing. The subject system has a dressing that is provided in three separate layers in an oval shape to allow for flexibility in treating wounds of various depths. The predicate dressing is a tubular shaped rod and is split along the longitudinal axis by the user for ease of configuring.

Bench and animal testing have demonstrated that the subject V.A.C VeraFlo Cleanse Choice Dressing System is substantially equivalent to the predicate V.A.C VeraFlo Cleanse Dressing System (K103156).