DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 9, 2016

KCI USA, Inc.
Kristen Hopewell
Senior Manager Risk Management and Post Market Surveillance
6203 Farinon Drive
San Antonio, Texas 78249

Re: K160487
Trade/Device Name: VAC Rx4 Negative Pressure Wound Therapy (NPWT) System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: November 4, 2016
Received: November 7, 2016

Dear Kristen Hopewell:

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)*
K160487

Device Name
V.A.C. Rx4 Negative Pressure Wound Therapy (NPWT) System

Indications for Use *(Describe)*
The V.A.C. Rx4 Negative Pressure Wound Therapy (NPWT) System is an integrated wound management system 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, it 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. 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.

The V.A.C. GranuFoam Silver™ Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types.

When used on closed surgical incisions, it is also 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.

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510(k) SUMMARY

V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System

Submitter Information [21 CFR 807.92(a)(1)]	
Name	KCI USA, Inc.
Address	6203 Farinon Drive San Antonio, TX 78249
Phone number	210-515-4162
Fax number	210-255-6727
Establishment Registration Number	3005178245
Name of contact person	Kristen Weniger Hopewell
Date prepared	November 4 2016
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System
Common or usual name	Negative Pressure Wound Therapy System
Classification name	Negative Pressure Wound Therapy Powered Suction Pump (and components)
Classification panel	General and Plastic Surgery
Regulation	21 CFR 878.4780
Regulatory Class	II
Product Code(s)	OMP
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	*Predicate 510(k) Numbers:* • InfoV.A.C.® Therapy System - K063740 (Market entry) • InfoV.A.C.® Therapy System - K120033 (Expanded Indication) *Reference 510(k) Numbers: Clearance of dressing systems/canisters for use with predicate InfoV.A.C. Therapy System:* • InfoV.A.C.® Therapy System for use with V.A.C.® Dressings (V.A.C.® GranuFoam Dressing, V.A.C.® GranuFoam Silver Dressing, V.A.C.® WhiteFoam™ Dressing) and InfoV.A.C.® 500ml and 1000ml Canisters - K063740 • Prevena™ Dressing with V.A.C.® Therapy System including InfoV.A.C.® Therapy System - K121883

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510(k) SUMMARY

V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System

	• KCI® NPWT Gauze Dressing with V.A.C.® Therapy System including InfoV.A.C.® Therapy System - K123507
Device description [21 CFR 807.92(a)(4)]	The V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System, model number 60600, is a therapy unit capable of providing Negative Pressure Wound Therapy for up to four wounds simultaneously with individual wound channel controls and feedback. The device is intended to be used only in acute care. The V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System consists of a four-channel therapy unit, disposable exudate canisters and dressings. The V.A.C.Rx4™ NPWT System utilizes the same KCI dressing systems and canisters that have been cleared for use with the predicate device system.

Currently Marketed Disposable System Components	Reference 510(k) Clearance of Disposable (most recent)
Canisters	
InfoV.A.C.® Canisters (500ml and 1000ml canisters)	K100657
Dressing system (consisting of dressing, drape and tubing set)	
V.A.C.® GranuFoam Dressing	K133276
V.A.C.® GranuFoam Silver Dressing	K133276
V.A.C.® WhiteFoam™ Dressing	K133276
Prevena™ Peel & Place and Prevena™ Customizable Prevena™ Peel & Place	K153199 K161897
KCI® NPWT Gauze Dressings	K133276

The software-controlled therapy unit applies a selectable range of negative pressure wound therapy to the wound bed or incision site. It can provide continuous or intermittent application of negative pressure wound therapy to the wound in the selectable range of 50mmHg to 200mmHg (in increments of 25mmHg). The dressing, to which the therapy unit is connected, enables distribution of the negative pressure wound therapy across the surface of the wound or incision, while the tubing transfers accumulated fluids such as wound exudates and infectious material to a disposable canister. The device can operate either by a mains power supply or internal battery.

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510(k) SUMMARY

V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System

Indications for use [21 CFR 807.92(a)(5)]	The V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System is an integrated wound management system 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, it 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. 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. The V.A.C. GranuFoam Silver™ Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types. When used on closed surgical incisions, it is also 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.

Comparison of the Technological Characteristics (i.e., design, material, chemical composition, energy source) with the Predicate Device [21 CFR 807.92(a)(6)]

Negative Pressure Wound Therapy is the technological principal for both the subject and the predicate device. The software-controlled therapy unit applies a selectable range of negative pressure wound therapy and modes. The dressing, to which the therapy unit is connected, enables distribution of the negative pressure wound therapy across the surface of the wound or incision, while the tubing transfers accumulated fluids such as wound exudates and infectious material to a disposable canister.

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

- The Negative Pressure Wound Therapy System includes a negative pressure wound therapy unit, canisters and dressings that are applied to an open wound or over an incision site. One of the following dressings may be selected by the clinician:
  - V.A.C.® Dressings (V.A.C.® GranuFoam, V.A.C.® GranuFoam Silver, V.A.C.® WhiteFoam™)
  - Prevena™ Peel & Place™ or Customizable™ Dressing
  - KCI® NPWT Gauze Dressing

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510(k) SUMMARY

V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System

- Fluid is collected into a disposable canister. One of the following canisters may be selected by the clinician:
  - InfoV.A.C.® 500 ml Canister
  - InfoV.A.C.® 1000 ml Canister
- The negative pressure wound therapy unit can provide continuous or intermittent application of negative pressure wound therapy in the selectable range of 50 - 200 mmHg (in increments of 25mmHg)
- The therapy unit provides alarms that indicate when negative pressure wound therapy may be compromised (e.g., visual and audible alarms indicating an air leak in the system, when the canister is full, canister not engaged, blockage, therapy inactive, pressure deviations, system errors, internal temperature or low battery).
- The device can operate either by a mains power supply or internal battery.

The following differences exist between the subject and predicate device:

- V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System has four independent channels whereas the predicate provides one therapy channel. Each therapy channel consists of its individual canister and an interface with associated controls to provide NPWT for that channel.
- The V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System contains additional alarms to monitor unit position and battery temperature.
- The software for the V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System does not contain optional help functions, patient versus clinician access, therapy setting guides, log tools, on screen therapy history information, or wound image / measurement features.
- The V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System is not intended to be used in the home care setting whereas the predicate is indicated for acute, extended and home care settings.

Performance Data [21 CFR 807.92(b)]

Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]

- Bench testing demonstrated that the V.A.C.Rx4™ is substantially equivalent to the InfoV.A.C.® Therapy Unit in the delivery of negative pressure wound therapy at 50, 125, and 200 mmHg under an air leak rate of 1.4 lpm in both continuous and intermittent modes and under both wet and dry conditions.
- Additionally, the ability of the V.A.C. Rx4™ Therapy Unit to provide NPWT within specification to each of the dressing configurations was confirmed for each channel. The ability of the therapy unit to control of negative pressure wound therapy, manage fluid and not generate false or unexpected alerts or alarms during normal operation was confirmed.

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510(k) SUMMARY

V.A.C.Rx4™ Negative Pressure Wound Therapy (NPWT) System

Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]
No clinical tests were necessary. However, the user interface was evaluated via simulated-use testing with users' representative of the use specification. Multiple formative evaluations led to the selection of an optimal user interface design in terms of use-safety and effectiveness. Summative usability evaluation of the final user interface design was performed using 15 subjects from three users groups (Surgeon/Physician, Surgical Scrub/Theatre Nurse, and Acute Care Nurse). Subjects performed approximately 50 usability tasks in a simulated use environment. The results of summative testing and a residual risk analysis demonstrate that intended users of the V.A.C. Rx4 Therapy System can safely and effectively perform critical tasks for the intended use in the expected use environment and that no use errors that may lead to unacceptable risk of harm are likely to occur. Risk levels [occurrence/severity] have been reduced as far as possible and any additional modifications would not further reduce risk.
Conclusions drawn [21 CFR 807.92(b)(3)]
The V.A.C.Rx4™ Negative Pressure Wound Therapy System and its predicate InfoV.A.C.® Therapy System (K063740 & K120033) are substantially equivalent in terms of safety, function and indications for use.