March 2, 2018

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

Re: K173447
Trade/Device Name: V.A.C.VIA 7 Day Therapy System Kit, V.A.C.VIA Therapy Starter Kit, V.A.C.VIA Negative Pressure Wound Therapy Unit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 31, 2018
Received: February 1, 2018

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.

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.

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,

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)*

K173447

Device Name
V.A.C.VIA Negative Pressure Wound Therapy System

Indications for Use *(Describe)*

The V.A.C.VIA™ Therapy System is an integrated wound management system for use in acute, extended and home care settings.

When used on open wounds, the V.A.C.VIA™ 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 exudates 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, the V.A.C.VIA™ is 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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.VIA™ Negative Pressure Wound Therapy Unit

Submitter Information [21 CFR 807.92(a)(1)]	
Name	KCI USA, Inc.
Address	6203 Farinon Drive San Antonio, TX 78249
Phone number	210-515-4059
Fax number	210-255-6727
Establishment Registration Number	30098970215
Name of contact person	Melanie Avila
Date prepared	February 27, 2018
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	V.A.C.VIA™ Negative Pressure Wound Therapy Unit
Common or usual name	Negative Pressure Wound Therapy Unit
Classification name	Negative Pressure Wound Therapy Powered Suction Pump
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)]	K132741
Device description [21 CFR 807.92(a)(4)]	The negative pressure technology for the subject device is the same as that of the predicate device. The therapy unit is a component of the therapy system which provides negative pressure wound therapy to the wound site for up to 7 days. Negative pressure is created by the therapy unit by means of one software-controlled diaphragm pump which allows for a lightweight, single use therapy unit that provides for negative pressure wound therapy at either -75 or -125 mmHg. Negative pressure is delivered to the wound site through tubing to a dressing placed over the wound site. An occlusive drape is placed over the dressing, which creates a sealed

510(k) SUMMARY

V.A.C.VIA™ Negative Pressure Wound Therapy Unit

	environment that helps maintain negative pressure and protects the wound from external contamination.
Indications for use [21 CFR 807.92(a)(5)]	The V.A.C.VIA™ Therapy System is an integrated wound management system for use in acute, extended and home care settings. When used on open wounds, the V.A.C.VIA™ 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 exudates 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, the V.A.C.VIA™ is 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)]

Similarities between the subject device and predicate device:

- A disposable negative pressure pump (therapy unit) provides negative pressure at either -125 mmHg or -75 mmHg for up to7 days.
- The dressings are connected to the therapy unit via a disposable canister and tubing set.
- Wound exudate is collected into the disposable canister
- 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 there is blockage, batteries are low).
- The therapy unit interface provides access to therapy via an On/Off button. It also provides alarm indicators, alarm mute button, power and battery indicators, as well as a therapy life indicator.
- The intended use and instructions for use are identical to that of the predicate device.

Differences between the subject and predicate device:

- Internal components of the therapy unit, such as the pump, boards, tubing and sensors have been updated to address obsolescence and manufacturability issues.
- The external power supply has also been updated.

Performance Data [21 CFR 807.92(b)]

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

510(k) SUMMARY

V.A.C.VIA™ Negative Pressure Wound Therapy Unit

- Bench testing demonstrated that the V.A.C.VIA™ Therapy Unit is substantially equivalent to the predicate therapy unit in the delivery of continuous negative pressure at 125 mmHg within specifications under worst case conditions of air leak rate and fluid input during a 3 and 7 day test.
- Electrical safety and electromechanical emissions testing confirm that the subject therapy unit meets the following standards:
    - ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)
    - IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests.
    - IEC 60601-6 Edition 3.1 2013-10 – Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability
    - IEC 60601-1-8 Edition 2.1 2012-11 Medical Electrical Equipment - Part 1-8: General Requirements for Basic Safety and Essential Performance - Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems In Medical Electrical Equipment and Medical Electrical Systems
    - IEC 60601-1-11 Edition 2.0 2015-01 - Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- The new lithium battery has been verified to meet IEC 62133 Edition 2.0 2012-12.

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. No usability testing was required, as there has been no change to the user interface or to the Instructions for Use.

Conclusions drawn [21 CFR 807.92(b)(3)]

The V.A.C.VIA™ Therapy Unit and its predicate unit are substantially equivalent in terms of safety, performance and indications for use.