K133741

NOV 15 2013

KCI

510(k) SUMMARY

V.A.C. ® Via™
Negative Pressure Wound Therapy System

Submitter Information [21 CFR 807.929(a)(1)]	
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive San Antonio, TX 78249
Phone number	210-515-4059
Fax number	210-255-6727
Establishment Registration Number	1625774
Name of contact person	Melanie Avila
Date prepared	08/23/2013
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	V.A.C. ® Via™ Negative Pressure Wound Therapy System
Common or usual name	Negative Pressure Wound Therapy System
Classification name	Negative Pressure Wound Therapy Powered Suction Pump
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. ® Via™ Negative Pressure Wound Therapy System, originally cleared under 510(k) K093526 and K120033
Device description [21 CFR 807.92(a)(4)]	Negative pressure wound therapy system
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, 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 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, it 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

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Negative Pressure Wound Therapy System

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]

Feature	V.A.C. ® Via™ NPWT System (Modified Device)			V.A.C. ® Via™ NPWT System (Predicate)		
Therapy unit	Same as predicate			Software controlled pump for delivery of negative pressure wound therapy		
• Operating Principle	Same as predicate			Software controlled pump for delivery of negative pressure wound therapy		
• Pump Type	One brushed, DC powered, single diaphragm pump			Two piezoelectric disc pumps		
• Software	Software code drives the operation of one conventional diaphragm pump			Software code drives the operation of two piezoelectric pumps		
• Housing Dimensions (inches)	Width	Length	Depth	Width	Length	Depth
	3.5	6.4	2.8	3.5	6.4	2.4
Therapy unit options	Same as predicate			Selectable negative pressure at either -125mmHg or -75mmHg		
Dressing system components	Same as predicate			System consists of Granufoam™ Dressing, interface pad and tubing, and adhesive 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)]

The V.A.C. ® Via™ NPWT System was evaluated to ensure conformance to the design specifications. The following bench tests were conducted:

- Performance testing to confirm therapy unit delivers negative pressure therapy
- Software verification and validation testing to confirm that therapy unit performs as designed
- Testing to confirm device meets all applicable electrical safety and electromagnetic compatibility standards.
- Battery life testing to demonstrate that the battery will supply adequate power to provide the appropriate negative pressure to the wound.

Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]

Not applicable

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

Testing indicates that the V.A.C. ® Via™ NPWT System is substantially equivalent in terms of both indications for use and fundamental scientific technology to the predicate product.

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

November 15, 2013

KCI USA, Incorporated
Ms. Melanie Avila
Regulatory Affairs Project Manager
6203 Farinon Drive
San Antonio, Texas 78249

Re: K132741
Trade/Device Name: V.A.C.® Via™ Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: October 14, 2013
Received: October 17, 2013

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 Mark N. Melkerson
Acting 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132741

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, 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 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, it 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S