510(k) SUMMARY

MAR 10 2010

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

Date prepared	February 26, 2010
510(k) owner	
• **Name**	KCI USA, Inc. (Kinetic Concepts, Inc.)
• **Address**	6203 Farinon Drive; San Antonio, Texas 78249
• **Phone number**	210 406-4602
• **Fax number**	210 255-6727
• **Name of contact person**	Randall Wheeland
Name of the device	
• **Trade or proprietary name**	*V.A.C.Via™ NPWT System*
• **Common or usual name**	Negative pressure wound therapy system
• **Classification name**	Negative pressure wound therapy powered suction pump (and components)
• **Legally marketed device(s) to which equivalence is claimed**	KCI ActiV.A.C.® Therapy System 510(k) Numbers: K063692 and K091585
Device description	
• **Device design**	The *V.A.C.Via™ NPWT System* consists of the following components: • A sterile dressing system applied to the wound and connected via tubing to a therapy unit that generates negative pressure at the wound • A sterile, disposable canister that collects wound exudates removed via the negative pressure
• **Intended use of the device**	The V.A.C.Via™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings. 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. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts

• **Summary of the technological characteristics of the device compared to the predicate device**	**Feature**	**V.A.C.Via™ NPWT System**	**Predicate NPWT System**
	Indicated wound types	Same	Chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts
	Therapy unit	Same	Software controlled, battery and AC powered negative pressure pump with a single use disposable fluid collection canister
	Foam dressing	Same except the acrylic adhesive of the drape has a different monomer composition which was chosen to improve sealing performance in the moist wound environment	V.A.C.® GranuFoam reticulated polyurethane foam wound dressing, adhesive drape made of polyurethane film with acrylic adhesive that creates a sealed wound environment, and interface pad and tubing set used to transfer negative pressure from the therapy unit to the wound, drawing exudates from the wound into the fluid collection canister
	The *V.A.C.Via™ NPWT* System and the predicate both create the same negative pressure wound healing environment.		
Summary of non-clinical tests conducted for determination of substantial equivalence	Testing in accordance to ISO 10993-1 standards was conducted for biocompatibility Testing in accordance to IEC 60601-1 and UL 60601-1 was conducted for electrical safety Testing in accordance to AAMI/ANSI/IEC 60601-1-2 was conducted for electromagnetic compatibility Testing in accordance to IEC 60601-1-6 was conducted for usability Testing in accordance to IEC 60601-1-8 was conducted for alarm systems The *V.A.C.Via™ NPWT* System and components were also evaluated to ensure conformance to design specifications and establish equivalence to the predicate device, as follows: • Verification and validation of software controls to ensure delivery of user selected negative pressure and continuous or intermittent therapy setting, pressure monitoring, and function of alarms		

	• Verification testing to ensure functional ability of the *V.A.C.Via™ NPWT System* to deliver continuous or intermittent negative pressure at either 75mmHg or 125mmHg and transfer wound exudates to a collection canister for up to seven days • Rheology and peel testing of the drape adhesive to demonstrate equivalent or improved intrinsic adhesive properties and peel strength respectively, as compared to the predicate drape adhesive • Human Factors testing to ensure inherent design features and labeling facilitate correct usage and effective response to alarms
Summary of clinical tests conducted for determination of substantial equivalence	None required for determining substantial equivalence
Conclusions drawn	Testing demonstrates that the *V.A.C.Via™ NPWT System* and *ActiV.A.C.® Therapy System* are substantially equivalent in terms of both indications for use and safe and effective delivery of negative pressure wound therapy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 10 2010

KCI USA, Inc.
% Mr. Randall Wheeland
Director, Regulatory Affairs
6203 Farinon Drive
San Antonio, Texas 78249

Re: K093526
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: II
Product Code: OMP
Dated: February 26, 2010
Received: March 1, 2010

Dear Mr. Wheeland:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093526
pg 1 of 1

INDICATIONS FOR USE

510(k) Number (if known): K093526

Device Name: *V.A.C.Via™ Negative Pressure Wound Therapy System*

Indications for Use:

The V.A.C.Via™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings. 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. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Posted November 13, 2003)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093526