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510(k) SUMMARY
V.A.C. VeraFlo Cleanse Dressing System

MAR 14 2011

Date prepared	February 16, 2011
510(k) owner	KCI, Inc.
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive; San Antonio, Texas 78249
Fax number	210 255-6727
Name of contact person	Margaret Marsh
Contact telephone number	1 800 275-4524; Request Regulatory Affairs.
Name of the device	
Trade or proprietary name	V.A.C. VeraFlo Cleanse Dressing System
Common or usual name	Negative pressure wound therapy dressing
Classification name	Dressing component for use with a Negative Pressure Wound Therapy Powered Suction Pump
Legally marketed device(s) to which equivalence is claimed	V.A.C. VeraFlo Dressing, a component of the V.A.C.Ulta Negative Pressure Wound Therapy System (K100657)
Device description	A dressing component of a negative pressure wound therapy system with an instillation feature which allows controlled delivery and drainage of topical wound treatment solutions and suspensions
Device design	Negative pressure wound therapy system, in which instillation of topical wound treatment solutions and suspensions and negative pressure wound therapy is provided via software controlled pumps. Instillation solutions and negative pressure are delivered through tubing to foam dressings in the wound covered by an occlusive drape. Software provides controls for both negative pressure wound therapy and delivery of instillation therapy. Software also provides controls for help and alarm functions.

Intended use of the device	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.		
Summary of the technological characteristics of the device compared to the predicate device.	**Feature**	**VeraFlo Cleanse Dressing**	**VeraFlo Dressing (predicate)**
	Dressing system components	Same as predicate	Foam based dressing with occlusive drape and negative pressure/ instillation tubing
	Patient contact materials of construction	Same as predicate, except for slightly less colorant	Polyurethane ester foam with polyurethane drape

Summary of tests conducted	The V.A.C. VeraFlo Cleanse System was evaluated under a number of design verification and validation tests that assure conformance to design specifications. The following tests were conducted on the V.A.C. VeraFlo Cleanse System: • Negative pressure distribution measurements (bench test with simulated wound model). • Visual observation of fluid distribution in the dressing and simulated wound bed (bench test with simulated wound model). • Mechanical properties (tensile and tear strength per ASTM 3574-08 tests) • Granulation tissue formation and wound fill response in an acute swine model. • Cytotoxicity, irritation, and sensitization testing was performed in accordance to ISO 10993-1 standards, and results demonstrated that the device is biocompatible according to these standards. The device was shown to meet all performance requirements.
Conclusions drawn	Testing demonstrates that the V.A.C. VeraFlo Cleanse System is substantially equivalent in terms of both indications for use and technology to the predicate product.

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

KCI USA
% Ms. Margaret Marsh
Regulatory Affairs Technical Director
6203 Farinon Drive
San Antonio, Texas 78249

MAR 14 2011

Re: K103156
Trade/Device Name: V.A.C. VeraFlo Cleanse Dressing System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: OMP
Dated: February 16, 2011
Received: February 17, 2011

Dear Ms. Marsh:

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

K103156

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: V.A.C. VeraFlo Cleanse Dressing System

Indications for Use:

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.

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)

David Krause for MKM

(Division Sign-Off) Page __ of ___

Division of Surgical, Orthopedic, and Restorative Devices

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(Posted November 13, 2003)