KCI

JUN - 7 2007

510(k) SUMMARY
ActiV.A.C.® Therapy Unit

Date prepared	May 31, 2007
510(k) Owner **Name** **Address** **Fax number**	 KCI USA, Inc. 8023 Vantage Drive, San Antonio, TX 78230 210 255-6727
Name of contact person	Margaret Marsh; Senior Manager, Regulatory Affairs
Name of the device **Trade or proprietary name** **Common or usual name** **Classification name**	 ActiV.A.C.® Therapy Unit Negative pressure wound therapy device Powered suction pump
Legally marketed device to which equivalence is claimed	The predicate device is the V.A.C. Freedom® Therapy Unit, which was cleared for market entry in the V.A.C.® Family of Products 510(k) K032310. It was also included in the V.A.C.® Therapy System 510(k) K062227 which provided text relating to the mechanism of action for inclusion into the Indications for Use statement.
Device description	The ActiV.A.C.® Therapy Unit is designed for the application of V.A.C.® Therapy in the acute, extended and home care settings. The software-controlled therapy unit applies negative pressure to the wound bed. The open cells of the V.A.C.® Foam Dressing to which the therapy unit is connected enable distribution of the negative pressure across the surface of the wound, while the tubing transfers accumulated fluids to the canister. The software monitors and maintains target pressure and alarms as needed to help assure target pressure is maintained and constant therapy is delivered. The safety features of the system include additional alarms, such as those that signal for tubing blockages, a full or missing collection canister, inactive therapy, low battery, and leaks in the seal of the dressing. Optional ancillary features include: Seal Check™ for identifying dressing leaks, a Therapy Settings Guide that provides options for therapy settings based on the recommendations in the KCI Clinical Guidelines, a screen guard feature that prevents unintentional screen changes, an exportable Therapy History Report via an IrDA or USB data port, and a Log Tool for recording canister changes, dressing changes and dressing pieces used.

KCI

Intended use of the device	The V.A.C.® 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 exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), 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.
Differences in intended use from the predicate	The intended use of the device has not changed from the predicate.
Summary of the technological characteristics of the device compared to the predicate device	ActiV.A.C.® Therapy Unit and the V.A.C. Freedom® Therapy Unit have the same technology and performance specifications for the delivery of negative pressure wound therapy. The ActiV.A.C.® Therapy Unit provides optional, ancillary features that make it easier to use by the caregiver and patient.
Summary of nonclinical tests	The new optional, ancillary features were evaluated under a number of verification and validation tests in order to assure conformance to design specifications.
Summary of clinical tests	A review of a large body of clinical data from randomized controlled trials, literature reports, and registry/MDR databases documents the safe use of the predicate V.A.C. Freedom® Therapy Unit in the home care setting. An engineering analysis of device performance documents that the ActiV.A.C.® and V.A.C. Freedom® are equivalent in the delivery of negative pressure wound therapy, and that ActiV.A.C.® improves upon V.A.C. Freedom® in the elements that affect safety and usability in the home care setting. This analysis concludes that the existing clinical data can be used to predict the safety of the ActiV.A.C.® Therapy System in the home care setting.

KCI®

Conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device	Verification and validation testing conducted under design control requirements document that the ActiV.A.C.® Therapy Unit and the predicate V.A.C. Freedom® Therapy Unit are equivalent in terms of technology and performance specifications for the delivery of negative pressure wound therapy. New optional ancillary features have been determined to meet performance specifications. Clinical data supporting the safe use of the V.A.C. Freedom® Therapy Unit in the home care setting are also applicable to the ActiV.A.C.® Therapy Unit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

KCI USA, Inc.
% Ms. Christy Oviatt
6203 Farinon Drive
San Antonio, Texas 78230

Re: K063692
Trade/Device Name: ActiV.A.C.® Therapy Unit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: May 1, 2007
Received: May 2, 2007

Dear Ms. Oviatt:

This letter corrects our substantially equivalent letter of June 7, 2007.

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 (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.

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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

For

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

Enclosure

KCI

INDICATIONS FOR USE

510(k) Number (if known): K063692
Device Name: ActiV.A.C.® Therapy Unit

Indications for Use:

The V.A.C.® 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 exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), 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.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063692

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

(Posted November 13, 2003)