K062227 Page 1/2

KCI

OCT - 4 2006

510(k) SUMMARY

Product Name: V.A.C.® Therapy System

Date prepared	September 27, 2006
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**	 V.A.C.® Therapy System Negative pressure wound therapy device Powered suction pump
Legally marketed device to which equivalence is claimed	Because the V.A.C.® Therapy System has not been modified for the purposes of this submission, the predicate products are the V.A.C.® Therapy Family of Products (Therapy Units ATS, Freedom and Instill and their associated disposable components), which were most recently cleared under 510(k)s: K032310 (V.A.C.® ATS and V.A.C.® Freedom® Therapy Units), K021501 (V.A.C.® Instill Therapy Unit), K053627 (V.A.C.® GranuFoam® Silver Protection Dressing) and K022011 (V.A.C.® Abdominal Dressing).
Device description	The components of the V.A.C.® Therapy System work as an integrated product to optimize both the delivery and the benefits of negative pressure. An open pore foam [reticulated polyurethane foam (GranuFoam®, GranuFoam® Silver, and Abdominal Dressings, etc.) or polyvinyl alcohol foam (Vers-Foam™ Dressing)] is cut to fit the wound, then covered with a semi-permeable adhesive drape. The software-controlled Therapy Unit applies negative pressure to the wound bed. The user can select continuous or intermittent therapy, depending upon wound type and the needs of each patient. The open cells of the foam enable equal distribution of the negative pressure across the surface of the wound, while the tubing transfers accumulated fluids to the canister. T.R.A.C.® (Therapeutic Regulated Accurate Care) technology 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.

K062227 page 2/2

KCI

Intended use of the device	The V.A.C. Therapy System 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.	
Summary of the technological characteristics of the device compared to the predicate device	**Design**	Same as predicates
	Materials	Same as predicates
	Energy Source	Same as predicates
Summary of nonclinical tests	Not applicable; no new nonclinical tests were performed for the purposes of this submission.	
Summary of clinical tests	Not applicable; no new clinical tests were performed for the purposes of this submission, except as described in the submitted literature.	
Conclusions	Published literature documenting the effective use of the V.A.C.® Therapy System in a variety of wound types and clinical situations support the following revision to the Indications for Use statement. The V.A.C.® Therapy System 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.	

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: K062227
Trade/Device Name: V.A.C.® Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: July 31, 2006
Received: August 2, 2006

Dear Ms. Oviatt:

This letter corrects our substantially equivalent letter of October 4, 2006.

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.

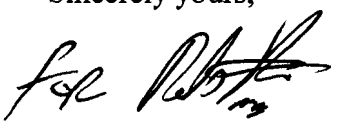
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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

Enclosure

INDICATIONS FOR USE

510(k) Number: K062227
Device Name: V.A.C.® Therapy System
Indications for Use:

The V.A.C. Therapy System 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.

Prescription Use ✓ (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)

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

Page __ of __

510(k) Number K062227