KCI

K063426

510(k) SUMMARY
V.A.C.® ATS Large (1000 mL) Canister With Gel

DEC 13 2006

Date prepared	November 10, 2006
510(k) Owner **Name** **Address** **Fax number**	 KCI USA, Inc. 8023 Vantage Drive, San Antonio, Texas 78230 210-255-6727
Name of contact person	Véronique Smith, Sr. Regulatory Affairs Specialist
Name of the device **Trade or proprietary name** **Common or usual name** **Classification name**	 V.A.C.® ATS Large (1000 mL) Canister With Gel Negative pressure wound therapy device Powered suction pump
Legally marketed device to which equivalence is claimed	The predicate product is the 500 mL V.A.C.® ATS Canister With Gel, described under K032310. This canister is a component of the V.A.C.® ATS Therapy Unit which was included in the V.A.C.® Family of Products 510(k) K032310 and the V.A.C.® Therapy System 510(k) K062227.
Device description	The V.A.C.® ATS Large (1000 mL) Canister With Gel is a sterile, single use canister that is inserted into the V.A.C.® ATS Therapy Unit to collect wound exudates. The V.A.C.® ATS 1000 mL Canister has volume graduations every 100 mL and contains two gel packs (isolyzers) for solidification of wound exudates. The 1000 mL canister is identical to the 500 mL canister cleared under K032310 except for volume capacity, the number of gel packs within the canister, and labeling.
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 for the device has not changed from the predicate.

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: K063426
Trade/Device Name: V.A.C.® ATS large Canister with Gel (1000ml)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: November 10, 2006
Received: November 13, 2006

Dear Ms. Oviatt:

This letter corrects our substantially equivalent letter of December 13, 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,

For Donna-Bea Tillman

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 (if known): _____
Device Name: V.A.C.® ATS Large (1000 mL) Canister With Gel
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 __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)

(Division Sign-Off)

(Posted November 13, 2003)

Division of General, Restorative, and Neurological Devices

510(k) Number K063426