K053627

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FEB 6 2006

510(k) Summary
V.A.C.® GranuFoam® Silver Protection Dressing

1. Submitter:	**KCI USA, Inc (Kinetic Concepts, Inc.)** **8023 Vantage Drive** **San Antonio, TX 78230**
2. Contact Person:	**Christy Oviatt** **Sr. Regulatory Affairs Specialist**
3. Date Summary Prepared:	**December 2, 2005**
4. Name of Device:	**V.A.C.® GranuFoam® Silver Protection Dressing**
5. Classification Name:	**Accessory to Powered Suction Pump** **21 CFR 878.4780** **Class II**
6. Predicate Devices:	**V.A.C.® GranuFoam® Silver Protection Dressing (K050261)**

7. Description of Device

The V.A.C.® GranuFoam® Silver Protection dressing is one of the V.A.C.® product line of dressings designed specifically for use with the V.A.C.® Family of negative pressure devices.

8. Indication for Use

The V.A.C.® GranuFoam® Silver Protection dressing is intended for use with the V.A.C.® family of negative pressure wound therapy systems to help promote wound healing. The dressing is an effective barrier to bacterial penetration and may help reduce infection in chronic, acute, traumatic, subacute, and dehisced wounds, diabetic ulcers, pressure ulcers, flaps, grafts and partial thickness burns.

9. Technological Characteristics and Substantial Equivalence

The V.A.C.® GranuFoam® Silver Protection dressing is comprised of black, reticulated, polyurethane foam covered with a silver coating.

The V.A.C.® GranuFoam® Silver Protection dressing is considered substantially equivalent to the V.A.C.® GranuFoam™ Silver Protection dressing (K050260). The only change is to the labeling for the dressing. A contraindication for use in magnetic resonance environments has been removed and labeling has been included for conditions of safe use in the magnetic resonance environment.

Verification of the conditions for safe use of the V.A.C.® GranuFoam® Silver Protection dressing in a magnetic resonance environment is based on testing in accordance with international performance standards and peer reviewed published literature.

10. Conclusion

Based on the information presented above it is concluded that the V.A.C.® GranuFoam® Silver Protection dressing can be marketed for its intended use and is substantially equivalent to the identified predicate devices.

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: K053627
Trade/Device Name: V.A.C.® GranuFoam® Silver Protection Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: December 28, 2005
Received: December 29, 2005

Dear Ms. Oviatt:

This letter corrects our substantially equivalent letter of February 6, 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 (if known):

Device Name: V.A.C.® GranuFoam® Silver Protection Dressing

Indications for Use:

The V.A.C.® GranuFoam® Silver Protection dressing is intended for use with the V.A.C.® family of negative pressure wound therapy systems to help promote wound healing. The dressing is an effective barrier to bacterial penetration and may help reduce infection in chronic, acute, traumatic, subacute, and dehisced wounds, diabetic ulcers, pressure ulcers, flaps, grafts and partial thickness burns.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephanie Kaufman for MKM

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

510(k) Number K053071