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KCI

DEC 15 2010

# 510(k) SUMMARY

## *V.A.C. GranuFoam Silver Protection Dressing*

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

| **Submitter Information [21 CFR 807.929(a)(1)]** | |
|---|---|
| **Name** | KCI USA, Inc. (Kinetic Concepts, Inc.) |
| **Address** | 6203 Farinon Drive<br>San Antonio, TX 78249 |
| **Phone number** | 210.515.4126 |
| **Fax number** | 210.255.6727 |
| **Establishment Registration Number** | 1625774 |
| **Name of contact person** | Shannon Scott, Regulatory Affairs Manager |
| **Date prepared** | December 14, 2010 |
| **Name of the device [21 CFR 807.92(a)(2)]** | |
| **Trade or proprietary name** | V.A.C. GranuFoam Silver® Protection Dressing |
| **Common or usual name** | Negative pressure wound therapy dressing |
| **Classification name** | Negative pressure wound therapy powered suction pump |
| **Classification panel** | General and Plastic Surgery |
| **Regulation** | 878.4780 |
| **Product Code(s)** | OMP |
| **Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]** | V.A.C. GranuFoam Silver Protection Dressing (K053627) |
| **Device description [21 CFR 807.92(a)(4)]** | The V.A.C. GranuFoam Silver Protection Dressing is a component of the V.A.C. Therapy System which is an integrated negative pressure wound management system. The dressing is polyurethane foam with a silver coating designed specifically for use with the V.A.C. family of negative pressure wound therapy devices. |
| **Indications for use [21 CFR 807.92(a)(5)]** | 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, partial thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. |

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# 510(k) SUMMARY
## *V.A.C. GranuFoam Silver Protection Dressing*

| **Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]** | | |
|---|---|---|
| **Characteristic** | **New Device**<br>*V.A.C. GranuFoam Silver Protection Dressing* | **Predicate**<br>*V.A.C. GranuFoam Silver Protection Dressing*<br>K053627 |
| Indications for use | *Same as predicate with the addition of venous insufficiency ulcers, cleared under 510(k) K091585.*<br><br>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, partial thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. | 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. |
| Dressing composition | Same as predicate | Black, reticulated, polyurethane foam with silver coating |
| Antibacterial activity | Same as predicate | Studies of antibacterial activity against S. aureus, P. aeruginosa, and E. coli. |
| **Performance Data [21 CFR 807.92(b)]** | | |
| **Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]** | | |
| Studies of the antibacterial activity of the predicate device were previously conducted against S. aureus, P. aeruginosa, and E. coli. In support of the proposed change to the product specification, testing has been conducted and the product has been shown to pass these tests with equivalent results. | | |
| **Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]** | | |
| No clinical tests were necessary. | | |
| **Conclusions drawn [21 CFR 807.92(b)(3)]** | | |
| The V.A.C. GranuFoam Silver Protection Dressing and its predicate (K053627) are identical in product design, composition and processing. V.A.C. GranuFoam Silver Protection Dressing is substantially equivalent to its predicate (K053627) in terms of safety, function and indications for use. | | |

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, Inc.
% Shannon Scott
Regulatory Affairs Manager
6203 Fairmon Drive
San Antonio, Texas 78249

DEC 15 2010

Re: K102956
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: November 22, 2010
Received: November 23, 2010

Dear Shannon Scott:

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

K102956

## INDICATIONS FOR USE

510(k) Number (if known): _____

DEC 15 2010

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, partial thickness burns, ulcers (such as diabetic, pressure or 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

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*(Posted November 13, 2003)*

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