510(k) SUMMARY

JUN 11 2010

Prevena™ Incision Management System

Date prepared	June 10, 2010
510(k) owner	KCI, Inc.
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive; San Antonio, Texas 78249
Fax number	210 255-6727
Name of contact person	Margaret Marsh
Contact telephone number	1 800 275-4524; Request Regulatory Affairs.
Name of the device	
Trade or proprietary name	Prevena™ Incision Management System
Common or usual name	Negative pressure wound therapy system
Classification name	Negative Pressure Wound Therapy Powered Suction Pump (and components)
Legally marketed device(s) to which equivalence is claimed	ActiV.A.C.® Therapy System (K063692 and K091585)
Device description	Negative pressure wound therapy system for application to surgically closed incisions.
Device design	The Prevena™ Incision Management System consists of the following components: • A single use, sterile **dressing** that is applied in a simple peel and place process. • Negative pressure is provided to the dressing via a negative pressure **therapy unit**. • Wound fluids are collected in a sterile, disposable **canister.** The Prevena™ Incision Management System is intended for continuous application of negative pressure wound therapy to the closed surgical incision immediately after surgery.
Intended use of the device	*The Prevena Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.*

<table>
<tr><td>Summary of the technological characteristics of the device compared to the predicate device</td><td>The subject device was found to be equivalent to the predicate device in delivery of negative pressure wound therapy to the indicated wound type. The devices are equivalent in terms of functional components.
<table>
<tr><th>Feature</th><th>Prevena™ Incision Management System</th><th>ActiV.A.C.® Therapy System</th></tr>
<tr><td>Indicated wound types</td><td>Surgical incisions, a subset of acute wounds</td><td>Chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts</td></tr>
<tr><td>Dressing</td><td>Single, one size, multi-layer dressing.</td><td>Multiple dressing components</td></tr>
<tr><td>Therapy unit</td><td>Single patient use only; battery powered</td><td>Multiple patient use; battery and AC powered</td></tr>
</table></td></tr>
<tr><td>Summary of tests conducted</td><td>The Prevena™ Incision Management System and components were evaluated under a number of design verification and validation tests in order to assure conformance to design specifications. This testing included::

Software verification and validation testing that confirm the ability of the software to meet all software requirements specifications.
Electromagnetic compatibility and electrical safety tests conducted per UL 60601-1 and EN 60601-1-2, documenting compliance with the standards.
Equivalency testing of the Prevena Incision Management System to the ActiV.A.C. Therapy System with respect to delivery of negative pressure wound therapy. Testing demonstrated that the two systems are equivalent under all test conditions.
The ability of the polyurethane shell of the dressing to serve as a microbial barrier (to protect the wound site from external contamination) was verified through a Phi-X 174 bacteriophage challenge of the polyurethane film. This testing indicated that there was no viral penetration.
The ability of the skin contact layer of the dressing to move fluid away from the skin was verified through a wicking study. The results confirmed that in the absence of negative pressure, the fabric has a high wicking capability for the test fluid. The study also confirmed that during this testing, silver ions did not migrate out of the fabric.
In vitro log reduction tests were conducted on the polyurethane-coated polyester fabric with silver. Tests were conducted without application of negative pressure and exposed samples of the fabric with silver to six log challenges of 6 species of microorganisms. Following inoculation, samples were tested for microbial counts immediately (day 0) and after incubation at 32° C in diluted nutrient broth for 1, 3, 5 and 7 days. The log reductions from the day 0 values are provided in the table below.

<table>
<tr><th rowspan="2">Challenge Organism</th><th colspan="4">Mean Log Reduction from Day 0</th></tr>
<tr><th>Day 1</th><th>Day 3</th><th>Day 5</th><th>Day 7</th></tr>
<tr><td>Escherichia coli (ATCC 8739)</td><td>2.2</td><td>4.0</td><td>3.9</td><td>4.5</td></tr>
</table></td></tr>
</table>

	Pseudomonas aeruginosa (ATCC 09027)	2.0	3.9	3.5	3.7

Challenge Organism	Mean Log Reduction from Day 0			
	Day 1	Day 3	Day 5	Day 7
Staphylococcus aureus (ATCC 6538)	1.6	3.6	3.6	3.5
Klebsiella pneumonia (ATCC 4352)	1.4	1.8	2.7	3.5
Candida albicans (ATCC 10231)	2.5	3.1	3.2	3.2
Aspergillus niger (ATCC 16404)	2.2	4.1	4.0	3.6

- Cytotoxicity, irritation, and sensitization testing was performed in accordance to ISO 10993-1 standards, and results demonstrated that the device is biocompatible according to these standards.
- A validation of the usability of the Prevena System in home care was assessed by two sets of participants – a simulated patient group (without health care experience) and a group of operating room nurses. Both studies confirmed the ability of the participants to use the therapy system, understand labeling and respond to alarms.

Conclusions drawn	Testing demonstrates that the Prevena™ Incision Management System and its predicate device are substantially equivalent in terms of both indications and technology, and that the System has the appropriate design characteristics for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

KCl USA, Inc.
% Ms. Margaret Marsh
Regulatory Affairs Technical Director
6203 Farinon Drive
San Antonio, Texas 78249

JUN 11 2010

Re: K100821
Trade/Device Name: Prevena™ Incision Management System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 28, 2010
Received: June 02, 2010

Dear Ms. Marsh:

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

K100820

INDICATIONS FOR USE

510(k) Number (if known): K100821

Device Name: Prevena™ Incision Management System

Indications for Use:

The Prevena Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

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)

(Posted November 13, 2003)

David Krause

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100621