K123878
p 1/2

JAN 15 2013

510(k) SUMMARY
Prevena Incision Management System with Customizable Dressing

Submitter Information [21 CFR 807.929(a)(1)]	
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive San Antonio, TX 78249
Phone number	210-515-4368
Fax number	210-255-6727
Establishment Registration Number	1625774
Name of contact person	Shannon Scott, Regulatory Affairs Senior Manager
Date prepared	December 14, 2012
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	Prevena Incision Management System with Customizable Dressing
Common or usual name	Negative Pressure Wound Therapy System
Classification name	Negative Pressure Wound Therapy Powered Suction Pump (and components)
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)]	Prevena Incision Management System with Customizable Dressing (K121883)
Device description [21 CFR 807.92(a)(4)]	Negative pressure wound therapy system for application to surgically closed incisions.
Indications for use [21 CFR 807.92(a)(5)]	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.

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]

The subject device was found to be equivalent to the predicate device in delivery of negative pressure to the indicated wound type. The devices are equivalent in terms of functional components.

Characteristic	**New Device** *Prevena™ Incision Management System with Customizable Dressing*	**Predicate** *Prevena™ Incision Management System with Customizable Dressing* K121883
Indicated wound types	Same as predicate	Closed surgical incisions
Dressing	Same as predicate	Multiple dressing components
Therapy unit	Same as predicate	Single patient use only; battery powered

K123878
p 2/2

KCI

Performance Data [21 CFR 807.92(b)]
Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]
The Prevena Incision Management System with Customizable Dressing was evaluated under a number of design verification and validation tests to assure safety, efficacy, conformance to design specifications and equivalence to the predicate device. The following tests were conducted: • Biocompatibility testing according to ISO 10993-1 • Equivalency testing with respect to delivery of negative pressure wound therapy
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)]
Testing demonstrates that the Prevena Incision Management System and its predicate (K121883) are substantially equivalent 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 Center – WO66-G609
Silver Spring, MD 20993-0002

KCI USA, Incorporated (Kinetics Concepts, Incorporated)
% Ms. Shannon Scott
Regulatory Affairs Senior Manager
6203 Farinon Drive
San Antonio, Texas 78249

January 15, 2013

Re: K123878
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: December 14, 2012
Received: December 17, 2012

Dear Ms. 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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123878

INDICATIONS FOR USE

510(k) Number (if known): K123878
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 Devices
510(k) Number _K123878_____