



Food and Drug Administration  
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February 29, 2016

Kinetic Concepts Incorporated USA  
Ms. Margaret Marsh  
Technical Director, Regulatory Affairs  
6203 Farinon Drive  
San Antonio, Texas 78249

Re: K153199

Trade/Device Name: Prevena Plus Incision Management System Kit With Peel & Place Dressing, Prevena Plus Peel & Place Dressing 5-pack, Prevena Plus Incision Management System Kit With Customizable Dressing, Prevena Plus Customizable Dressing 5-pack

Regulation Number: 21 CFR 878.4780

Regulation Name: Powered Suction Pump

Regulatory Class: Class II

Product Code: OMP

Dated: February 1, 2016

Received: February 3, 2016

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K153199

Device Name

Prevena Plus Incision Management System with Peel & Place and Customizable Dressings

Indications for Use (Describe)

The Prevena Plus 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) SUMMARY

### Prevena Plus Incision Management System

<b>Submitter Information [21 CFR 807.92(a)(1)]</b>	
<b>Name</b>	KCI USA, Inc. (Kinetic Concepts, Inc.)
<b>Address</b>	6203 Farinon Drive San Antonio, TX 78249
<b>Phone number</b>	210-255-6481
<b>Fax number</b>	210-255-6727
<b>Establishment Registration Number</b>	3005178245
<b>Name of contact person</b>	Margaret Marsh, Technical Director, Regulatory Affairs
<b>Date prepared</b>	February 22, 2016
<b>Name of the device [21 CFR 807.92(a)(2)]</b>	
<b>Trade or proprietary name</b>	<b>Prevena Plus Incision Management System with Peel &amp; Place and Customizable Dressings</b>
<b>Common or usual name</b>	<b>Negative Pressure Wound Therapy System</b>
<b>Classification name</b>	<b>Negative Pressure Wound Therapy Powered Suction Pump (and components)</b>
<b>Classification panel</b>	<b>General and Plastic Surgery</b>
<b>Regulation</b>	<b>878.4780</b>
<b>Regulatory Class</b>	<b>II</b>
<b>Product Code(s)</b>	OMP
<b>Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]</b>	<i>Prevena Incision Management System with Peel &amp; Place and Customizable Dressings (as cleared under K141017)</i>
<b>Device description [21 CFR 807.92(a)(4)]</b>	<p>The <i>Prevena Plus Incision Management System</i> provides surgical incision management via the application of negative pressure wound therapy over an incision site that has been surgically closed with sutures or staples. The system is applied to the incision site immediately after surgery for a minimum of 2 days up to a maximum of 7 days depending on the surgeon's preference. The <i>Prevena Plus Incision Management System</i> consists of:</p> <ul style="list-style-type: none"> <li>• A <i>Prevena Dressing (Prevena Plus Peel &amp; Place Dressing or Prevena Plus Customizable Dressing)</i> and</li> <li>• One of the following KCI Negative Pressure Wound Therapy Units: <ul style="list-style-type: none"> <li>○ <i>Prevena Plus 125 Therapy Unit*</i></li> <li>○ <i>ActiV.A.C. Therapy Unit</i></li> <li>○ <i>V.A.C. Freedom Therapy Unit</i></li> <li>○ <i>InfoV.A.C. Therapy Unit</i></li> <li>○ <i>V.A.C. ATS Therapy Unit</i></li> <li>○ <i>V.A.C. Ultra Therapy Unit</i></li> </ul> </li> </ul> <p>* The <i>Prevena Plus 125 Therapy Unit</i> is a slightly modified <i>V.A.C. Via Therapy Unit</i>, previously cleared under K132741, that provides continuous negative pressure at -125mmHg only. The <i>V.A.C. Via Therapy Unit</i> serves as a reference device for 510(k) K153199.</p>

<b>Indications for use</b> <b>[21 CFR 807.92(a)(5)]</b>	The Prevena Plus 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.		
<b>Summary of the technological characteristics of the device compared to the predicate device</b> <b>[21 CFR 807.92(a)(6)]</b>			
Negative Pressure Wound Therapy is the technological principal for both the subject and predicate devices. Application of negative pressure to an incision site that is closed via staples or sutures helps draw the incision edges together and removes fluid from the incision site. The occlusive drape of the dressing provides a negative pressure environment and protects the incision from external contamination.			
The subject device system ( <i>Prevena Plus Incision Management System</i> ) is comprised of previously cleared components as shown below:			
Component	<b>Predicate Device:</b> <i>Prevena Incision Management System</i> (K141017)	<b>Reference Device:</b> <i>V.A.C. Via Negative Pressure Wound Therapy System</i> (K132741)	<b>Reference Device:</b> <i>V.A.C. Negative Pressure Wound Therapy Systems</i> (K120033)
Indications for Use	Identical to Predicate	Not applicable	Not applicable
Dressings	Identical to the Predicate <i>Prevena Peel &amp; Place</i> and <i>Customizable Dressings</i>	Not applicable	Not applicable
Therapy Units and Canisters	Identical to the Predicate <i>Acti V.A.C, Info V.A.C., V.A.C.Ultra</i> and <i>V.A.C. Freedom Therapy Units</i>	The <i>Prevena Plus 125 Therapy Unit</i> is identical to the reference <i>V.A.C. Via Therapy Unit</i> cleared under K132741, except for removal of options for intermittent and -75 mmHg therapy	Not applicable
Tubing Set	Not applicable	Not applicable	<i>SensaT.R.A.C.</i> tubing set
Labeling	Includes Predicate <i>Prevena Incision Management System</i> safety information and dressing application instructions	Includes Reference <i>V.A.C.Via Therapy Unit</i> operating instructions and alarm resolution information.	Not applicable

**Summary of the technological characteristics of the device compared to the predicate device, continued**

**At a high level, the subject device and predicate device are based on the following same technological elements:**

- The dressings that are applied over the incision site in the operating room are identical. One of the following dressings may be selected by the surgeon, based on incision length and geometry:
  - The *Prevena Plus Peel & Place Dressing* which can be used for linear incisions up to 8 inches, or
  - The *Prevena Plus Customizable Dressing* which can be configured for non-linear incisions or linear incisions longer than 8 inches
- A negative pressure pump (therapy unit) is required that can provide -125 mmHg of negative pressure continuously to the dressing for a maximum of 7 days.
- The dressings are connected to the therapy unit via a disposable canister and tubing set.
- Incision fluid is collected into the disposable canister
- The therapy unit provides alarms that indicate when negative pressure wound therapy may be compromised (e.g., visual and audible alarms indicating an air leak in the system or when the canister is full).

The following technological differences exist between the subject and predicate devices:

- Connection between the dressings and therapy unit canisters is via a *SensaT.R.A.C.* tubing set rather than by a *Prevena* tubing set. This allows for pressure sensing at the incision site for all of the indicated therapy units.
- Use of the *Prevena Plus 125 Therapy Unit* requires a connector (*Prevena Plus Connector*) to connect the *SensaT.R.A.C.* tubing to the canister. No tubing connector is required for use of all of the other indicated therapy units.
- Comparing the *Prevena Plus 125 Therapy Unit* to the *Prevena 125 Therapy Unit*, there are the following technological differences:
  - The *Prevena Plus 125 Therapy Unit* is both AC and battery powered, whereas the *Prevena 125 Therapy Unit* is powered by batteries only.
  - The *Prevena Plus 125 Therapy Unit* is provided with either a 150 or 250 cc canister, whereas the *Prevena 125 Therapy Unit* has a 45 cc canister.
  - The *Prevena Plus 125 Therapy Unit* provides a shared blockage/canister full alert whereas the *Prevena 125 Therapy Unit* has a canister full alert.

**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 following performance data were provided in support of the substantial equivalence determination.

- The average distribution of negative pressure across the full length of the *Prevena Plus Customizable Dressing* on a simulated wound bed under wet conditions and at maximum air leak demonstrated that the *Prevena Plus 125 Therapy Unit* and tubing set were able to provide negative pressure within specification at -125 mmHg, continuous mode for 7 days, equivalent to both the predicate and reference therapy units.
- The *Prevena Plus 125 Therapy Unit* was shown to provide alarms for leak, blockage and full canister within specification when connected to the *Prevena Plus Customizable Dressing* and tubing set.

**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 *Prevena Plus Incision Management System* and its predicate, the *Prevena Incision Management System* (K141017) are substantially equivalent in terms of safety, function and indications for use.