January 26, 2017

KCI USA, Inc. (Kinetic Concepts, Inc.)
Margaret Marsh
Regulatory Affairs Technical Director
6203 Farinon Drive
San Antonio, Texas 78249

Re: K162790
  Trade/Device Name: V.A.C. Ulta Negative Pressure Wound Therapy System
  Regulation Number: 21 CFR 878.4780
  Regulation Name: Powered Suction Pump
  Regulatory Class: Class II
  Product Code: OMP
  Dated: December 29, 2016
  Received: December 30, 2016

Dear Margaret 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,

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
Device Name
V.A.C.ULTA Negative Pressure Wound Therapy System

Indications for Use (Describe)

The V.A.C.ULTA™ Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy with an instillation option.

• Negative Pressure Wound Therapy in the absence of instillation is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.

• Instillation Therapy is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The V.A.C.ULTA™ Negative Pressure Wound Therapy System with and without instillation is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.

• Negative Pressure Wound Therapy in the absence of instillation may also be used for:
  o The temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary and for open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater.
  o The management of 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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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
### 510(k) SUMMARY

**V.A.C.ULTA™ Negative Pressure Wound Therapy System**

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<thead>
<tr>
<th>Date prepared</th>
<th>January 24, 2017</th>
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**Submitter information [21 CFR 807.929(a)(1)]**

<table>
<thead>
<tr>
<th>Name</th>
<th>KCI USA, Inc. (Kinetic Concepts, Inc.)</th>
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<tbody>
<tr>
<td>Address</td>
<td>6203 Farinon Drive; San Antonio, Texas 78249</td>
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<tr>
<td>Fax number</td>
<td>210 255-6727</td>
</tr>
<tr>
<td>Establishment Registration Number</td>
<td>3009897021</td>
</tr>
<tr>
<td>Name of contact person</td>
<td>Margaret Marsh, Technical Director, Regulatory Affairs</td>
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**Name of the device [21 CFR 807.92(a)(2)]**

| Trade or proprietary name | V.A.C.ULTA™ Negative Pressure Wound Therapy System (V.A.C.ULTA™ Therapy System) |
| Common or usual name | Negative pressure wound therapy system with an instillation option |
| Classification name | Negative Pressure Wound Therapy Powered Suction Pump (and components) |

**Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]**

V.A.C.ULTA™ Negative Pressure Wound Therapy System (K100657)

**Device description [21 CFR 807.92(a)(4)]**

The V.A.C.ULTA™ Negative Pressure Wound Therapy System is a negative pressure wound therapy system with an instillation feature which allows controlled delivery and drainage of topical wound treatment solutions and suspensions. The unit is comprised of a vacuum pump and an instillation pump. The vacuum pump delivers negative pressure therapy for the removal of wound exudate and when applicable instilled solutions. The instillation pump provides controlled delivery of topical wound solutions and suspensions. Both pumps are software controlled. Instillation solutions and negative pressure are delivered through tubing to foam dressings in the wound covered by an occlusive drape. Software monitors both negative pressure during negative pressure wound therapy as well as positive pressure during instillation of fluids to the wound bed. Software also provides controls for help and alarm functions.

**Indications for Use [21 CFR 807.92(a)(5)]**

The V.A.C.ULTA™ Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy with an instillation option.

- Negative Pressure Wound Therapy in the absence of instillation is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.
- Instillation Therapy is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

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510(k) SUMMARY
V.A.C.ULTA™ Negative Pressure Wound Therapy System

Abdominal dressing will most often be applied in the operating theater.
- The management of 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.

Comparison of the technological characteristics with the predicate device [21 CFR 807.92(a)(6)]

At a high level, the subject devices and predicate devices are based on the following same technological elements:
- Both device systems provide the same previously indicated therapies (V.A.C. Therapy, V.A.C.VERAFLO Therapy, PREVENA Incision Management Therapy and ABTHERA Open Abdomen Therapy.
- They both use the same dressing components and therapy unit disposables.
- They both have the same technology and specifications or delivery of negative pressure and instillation therapies.

The following technological differences exist between the subject and predicate devices:
The V.A.C.ULTA Therapy Unit software has been revised to provide the following user enhancements:
- The therapy unit now provides on screen options for selection of labeled parameters for PREVENA and ABTHERA Therapies; the options also provide therapy specific alert notifications and help features.
- There are now updated user pathways for the V.A.C. and VERA FLO Therapy settings to allow for immediate selection of the default settings with an advanced settings pathway option for experienced users.
- Optional ancillary features have been added to facilitate use, such as a Wound Imaging Tool, History Tool to access therapy, patient and alarm histories, and an Information Tool to access current therapy settings.

Performance Data [21 CFR 807.92(b)]

Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]

- Software has been assessed in accordance with FDA Guidance, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005.
- Therapy unit has been certified as conforming with the following electrical safety and electromagnetic standards:
- Negative pressure performance testing was conducted using simulated wound exudate, maximum air leak rate, worst case dressing configuration and for the maximum use life of the dressings. The results documented that selection of PREVENA and ABTHERA Therapy settings on the Therapy Unit resulted in delivery of negative pressure within established parameters for PREVENA Therapy (-125 mmHg, continuous mode) and for ABTHERA Therapy (-100, -125 and -150 mmHg, continuous mode).

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. However human factors engineering assessment with 30 subject nurses
and doctors indicated that the new features could be safely and effectively used by all test subjects.

<table>
<thead>
<tr>
<th><strong>Conclusions drawn [21 CFR 807.92(b)(3)]</strong></th>
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<tr>
<td>The subject device with software modifications is equivalent to the predicate device:</td>
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<tr>
<td>• There has been no change to the intended use of the unit; the proposed modifications to the indications for use statement reflect a consolidation of uses for which the therapy unit has been previously cleared.</td>
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<tr>
<td>• There has been no change to the technology delivering negative pressure and instillation therapy. Performance specifications remain unchanged.</td>
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<tr>
<td>• Human factors engineering assessment documents that the changes to the therapy unit software and its associated labeling to provide ease of use features are safe and effective for their intended use.</td>
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