September 12, 2019

KCI USA, Inc.
Teri Feeley
Sr. Regulatory Specialist
6203 Farinon Dr.
San Antonio, Texas 78249

Re: K183543
Trade/Device Name: ACTIV.A.C. Therapy Unit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: December 19, 2018
Received: December 20, 2018

Dear Teri Feeley:

This letter corrects our substantially equivalent letter of March 20, 2019.

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 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang -S

Cynthia J. Chang, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K183543

Device Name

ACTIV.A.C.™ Therapy Unit

Indications for Use *(Describe)*

The ACTIV.A.C.™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings.

When used on open wounds, it 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. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

When used on closed surgical incisions, it 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 exudates via the application of negative pressure wound therapy.

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

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

ACTIV.A.C.™ Therapy Unit

KCI USA, Inc.
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Phone: 210-515-4396
Facsimile: 210-255-6727
Contact Person: Teri Feeley
Date Prepared: 20 Mar 2019

Name of Device: ACTIV.A.C.™ Therapy Unit

Common or Usual Name: Negative Pressure Wound Therapy Unit

Classification Name: Negative Pressure Wound Therapy Powered Suction Pump (and components)

510(k) Number: K183543

Regulatory Number: 21 CFR 878.4780

Regulatory Class: II

Product Code: OMP

Predicate Device

KCI USA, Inc., ACTIV.A.C.™ Therapy Unit (K063692, K120033)

Device Description

The ACTIV.A.C.™ Therapy Unit is a component of the ACTIV.A.C.™ Negative Pressure Wound Therapy (NPWT) System. The ACTIV.A.C.™ Negative Pressure Wound Therapy (NPWT) system consists of:

- ACTIV.A.C.™ Therapy Unit (the subject of this submission)
- disposable canister which collects wound exudate
- a wound interface dressing
- semi-occlusive wound drape
- sensing pad and lumen

The ACTIV.A.C.™ Therapy Unit is a portable, battery-powered, reusable, software-controlled therapy unit that can provide continuous or intermittent applications of negative pressure to the wound bed in the selectable range of -25mmHg to -200mmHg. The ACTV.A.C.™ Therapy Unit is designed for the application of Negative Pressure Wound Therapy in the home, acute or extended care setting. The open cells of the dressing, to which the therapy unit is connected via pad and lumen, enables distribution of the negative pressure across the surface of the wound bed, while the

tubing transfers accumulated fluids to the canister. The software monitors and maintains target pressure and alarms as needed to help assure target pressure is maintained and constant therapy is delivered. The safety features of the system include additional alarms, such as those that signal for tubing blockages, a full or missing collection canister, inactive therapy, low battery, and leaks in the seal of the dressing.

Optional ancillary features include: Seal Check™ for identifying dressing leaks, a Therapy Settings Guide that contains preset therapy settings based on wound type, a screen guard feature that prevents unintentional screen changes, an exportable Therapy History Report via USB data port, and a Log Tool for recording canister changes, dressing changes and dressing pieces used.

Intended Use / Indications for Use

The ACTIV.A.C.™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings.

When used on open wounds, it 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. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

When used on closed surgical incisions, it 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 exudates via the application of negative pressure wound therapy.

Summary of Technological Characteristics

Controlled delivery of negative pressure to the wound site is the technological principle for both the subject and predicate devices. The software-controlled therapy unit applies negative pressure to the wound bed. The open cells of the dressing, to which the therapy unit is connected via pad and lumen, enables distribution of the negative pressure across the surface of the wound bed, while the tubing transfers accumulated fluids to the canister. At a high level, the subject and predicate devices are based on the following same technological elements:

- Intended use
- Indicated wound types
- ACTIV.A.C. Therapy System dressing components and canister
- Software controlled negative pressure pump and negative pressure specifications
- Use environment is acute, extended and home care settings

The following minor design differences exist between the subject and the predicate device as cleared under K063692:

Changes associated with this submission:

- Additional and modified gaskets on the ACTIV.A.C.™ Therapy Unit housing for improved fluid ingress protection for added safety.
- Expanded storage temperature specifications to demonstrate the device functions as intended if exposed to more rigorous storage environments.

In addition, the submission summarized minor device modifications implemented since the time of predicate device clearance that could not significantly affect device safety or effectiveness and thereby did not require 510(k) submissions. These include routine component updates to address component obsolescence and device manufacturability, minor software updates, upgraded power supply and power connector, and canister modifications.

A table comparing the key features of the subject and predicate devices is provided below.

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

Characteristic	Subject Device: ACTIV.A.C.™ Therapy Unit	Predicate Device: ACTIV.A.C.™ Therapy Unit (K063692)	Predicate Device: ACTIV.A.C.™ Therapy Unit (K120033)
Intended Use	Identical to K120033	To deliver and maintain negative pressure wound therapy to the wound site.	To deliver and maintain negative pressure wound therapy to the open wound site and closed surgical incision.
Indicated Wound Types	Identical to K120033	• Chronic • Acute • Traumatic • Subacute • Dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic, pressure or venous insufficiency) • Flaps and grafts	• Chronic • Acute • Traumatic • Subacute • Dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic, pressure or venous insufficiency) • Flaps and grafts • Surgically closed incisions
Negative Pressure Wound Therapy System Components	Identical	• ACTIV.A.C.™ Therapy Unit • Disposable canister which collects wound exudate • A wound interface dressing • Semi-occlusive wound drape • Sensing pad and lumen	• ACTIV.A.C.™ Therapy Unit • Disposable canister which collects wound exudate • A wound interface dressing • Semi-occlusive wound drape • Sensing pad and lumen
Use environment/Care Setting	Identical	Acute, extended and home care settings	Acute, extended and home care settings
Negative Pressure Unit Pump	Identical	Brushless, DC powered, double diaphragm pump	Brushless, DC powered, double diaphragm pump
Negative pressure options	Identical	25-200 mmHg, 25mmHg increments	25-200 mmHg, 25mmHg increments

Performance Data

Summary of non-clinical tests conducted for determination of substantial equivalence:

- Conformance to the most current General Requirements for Basic Safety and Essential Performance 60601-1 standards.
- Software has been assessed in accordance with FDA *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* (May 11, 2005).
- ACTIV.A.C.™ Negative Pressure Maintenance System Test demonstrates the ACTIV.A.C.™ Therapy Unit maintains negative pressure within specifications and manages fluid exudate without unexpected alarms.

- ACTIV.A.C.™ Therapy Unit Extreme Environmental Storage Conditions test demonstrates the therapy unit functions as intended when exposed to wider temperature specifications.

In all instances, the ACTIV.A.C.™ Therapy Unit functioned as intended and all test results observed were as expected.

Human factors engineering testing was not required since the subject device has the same user interface and use environment as the predicate.

Conclusions

The ACTIV.A.C.™ Therapy Unit is as safe and effective as the predicate ACTIV.A.C.™ Therapy Unit (K063692). The subject device's fundamental technology and principles of operation for the ACTIV.A.C.™ Therapy Unit are unchanged compared to the predicate device as cleared under K063692. The subject device's Intended Use remains unchanged from the predicate device as cleared under K063692. The Indications for Use for the ACTIV.A.C. was recently modified to include closed incisions under K120033, which was cleared in 2012. Therefore, the Intended Use/Indications for Use for the subject device remain unchanged

The minor technological differences between the ACTIV.A.C.™ Therapy Unit and its predicate device could not significantly affect the safety or effectiveness of the device, nor did they represent a major change in intended use safety. The performance data demonstrates that the ACTIV.A.C.™ Therapy Unit is as safe and effective as the predicate. Thus, the ACTIV.A.C.™ Therapy Unit is substantially equivalent to the predicate.