July 8, 2020

KCI USA, Inc
Jesus Valencia
Sr. Associate, Regulatory Affairs
6203 Farinon Drive
San Antonio, Texas 78249

Re: K201571
Trade/Device Name: ACTIV.A.C. Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: June 10, 2020
Received: June 11, 2020

Dear Jesus Valencia:

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. 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,

Anjana Jain, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*
K201571

Device Name
ACTIV.A.C.™ Negative Pressure Wound Therapy System

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)*

☒ 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.™ Negative Pressure Wound Therapy System

Submitter Information [21 CFR 807.929(a)(1)]	
Name	KCI USA, Inc.
Address	6203 Farinon Drive San Antonio, TX 78249
Phone number	210-515-4012
Fax number	210-255-6727
Establishment Registration Number	3005178245
Name of contact person	Jesus Valencia
Date prepared	July 1, 2020
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	ACTIV.A.C.™ Negative Pressure Wound Therapy System
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	21 CFR 878.4780
Product Code(s)	OMP
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	KCI USA, Inc., ACTIV.A.C.™ Therapy Unit (*cleared as a component of the ACTIV.A.C.™ Negative Pressure Wound Therapy System under K183543*)
Device description [21 CFR 807.92(a)(4)]	The ACTIV.A.C.™ Therapy Unit is a component of the ACTIV.A.C.™ Negative Pressure Wound Therapy System, also referred to as the ACTIV.A.C.™ Therapy System. The ACTIV.A.C.™ Therapy System consists of: • an ACTIV.A.C.™ Therapy Unit *(the subject of this submission),* • a disposable canister which collects wound exudate, • a wound interface dressing, • a semi-occlusive wound drape, and • a 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 fluids removed from the wound to the canister. The therapy unit's 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.
Indications for use [21 CFR 807.92(a)(5)]	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.

Comparison of the Technological Characteristics (i.e., design, material, chemical composition, energy source) with the Predicate Device [21 CFR 807.92(a)(6)]

Controlled delivery of negative pressure to the wound site is the technological principle for both the subject and predicate device. 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 fluids removed from the wound to the canister.

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

- Intended use
- Indications for use
- Indicated wound types
- ACTIV.A.C.™ Therapy System components: wound interface dressing, drape, canister and sensing pad and lumen
- Software controlled negative pressure pump and negative pressure specifications
- Use environment (acute, extended and home care settings)

The following minor design differences exist between the subject and predicate device as cleared under K183543:

- Added a confirmation screen to provide a visual and audible notification to the user prior to device shutdown. The therapy unit will continue delivering therapy and will not power off until the user acknowledges via touchscreen that the intent is to power off the unit.
- Modified the power button component for improved rigidity and robustness.

In addition, this submission summarizes other minor modifications implemented since the time of predicate device clearance that do not significantly affect device safety or effectiveness and thereby did not require a 510(k) submission. These minor modifications include routine component updates to address component obsolescence and minor software updates.

Performance Data [21 CFR 807.92(b)]
Summary of tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]
Bench testing demonstrated that the subject ACTIV.A.C.™ Therapy Unit is substantially equivalent to its predicate device. The software modifications were developed, tested and assessed according to FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)* and FDA-recognized standard *IEC 62304:2006/Amd 1:2015)*. The modified power button component was tested according to the following standards prior to and after being subjected to a predetermined number of cycles: • Force/ Displacement: *ASTM F2592-16* • Circuit Resistance: *ASTM F1680-07a(2014)* • Contact Bounce: *ASTM F1661-09(2015)* • Visual Inspection: *ASTM F1595-00(2012)* • Contact Closure Cycling: *ASTM F1578-07(2014)* In all instances, test results indicate that the subject device complies with its predetermined specifications and the applicable FDA guidance and standards. Clinical and pre-clinical testing were not necessary to demonstrate substantial equivalence. A usability assessment was conducted and concluded the device modifications described in this submission do not require additional usability testing. The usability assessment was conducted in accordance with the applicable guidelines listed in FDA Guidance Document: *Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016)* and in FDA-recognized standards: *IEC 62366-1:2015* and *ANSI/AAMI HE75:2009*.
Conclusions drawn [21 CFR 807.92(b)(3)]
The subject device's intended use, indications for use, fundamental technology and principles of operation are unchanged compared to the predicate device as cleared under K183543. The minor technological differences between the subject ACTIV.A.C.™ Therapy Unit provide additional safety features to further mitigate existing risks, do not significantly affect the effectiveness of the device and do not represent a major change in user tasks or interactions. The subject device is as safe and effective as the predicate device. Thus, the subject ACTIV.A.C.™ Therapy Unit is substantially equivalent to its predicate.