November 22, 2019

KCI USA, Inc.
Patricia Lopez
Sr. Regulatory Affairs Specialist
6203 Farinon Drive
San Antonio, Texas 78249

Re: K190697
Trade/Device Name: PREVENA PLUS Incision Management System (No Ag)
PREVENA PLUS DUO Incision Management System (No Ag)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: October 23, 2019
Received: October 24, 2019

Dear Patricia Lopez:

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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (acting)
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)*

Device Name
PREVENA PLUS™ Incision Management System (No Ag)

Indications for Use *(Describe)*
The PREVENA PLUS Incision Management System (No Ag) 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
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."

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)*

Device Name
PREVENA PLUS DUO™ Incision Management System (No Ag)

Indications for Use *(Describe)*
The PREVENA PLUS DUO Incision Management System (No Ag) 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.

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510(K) SUMMARY

Submitter Information [21 CFR 807.929(a)(1)]	
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive San Antonio, TX 78249
Establishment Registration Number	1625774
Contact person, by name, title, phone number, fax number and e-mail address	Shannon Scott Senior Director, Regulatory Affairs Telephone: (210) 515-7433 E-mail: Shannon.Scott@Acelity.com
Alternate contact person, by name, title, phone number, fax number and e-mail address	Terrie McDaniel Interim VP, Global Regulatory Affairs Telephone: (210) 515-4248 E-mail: Terrie.McDaniel@Acelity.com
Date prepared	22 Nov 2019
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	• PREVENA PLUS Incision Management System (No Ag) • PREVENA PLUS DUO Incision Management System (No Ag)
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 PLUS Incision Management System (K173426) • PREVENA PLUS DUO Incision Management Systems with PEEL & PLACE Dressings (K161897)
Device description [21 CFR 807.92(a)(4)]	• PREVENA PLUS Incision Management System with PREVENA PEEL & PLACE Dressing (No Ag) with SENSAT.R.A.C. Technology • PREVENA PEEL & PLACE Dressing (No Ag) with SENSAT.R.A.C. Technology

	• PREVENA PLUS Incision Management System with PREVENA PLUS CUSTOMIZABLE Dressing (No Ag) • PREVENA PLUS CUSTOMIZABLE Dressing (No Ag) with SENSAT.R.A.C. Technology • PREVENA PLUS DUO Incision Management System with PEEL & PLACE Dressings (No Ag) with SENSATRAC Technology Negative pressure wound therapy system for application to surgically closed incisions. The system consists of a therapy unit (PREVENA PLUS™ 125 Therapy Unit, ACTIVAC™ Therapy Unit, V.A.C. ULTA™ Therapy Unit, or V.A.C. RX4™ Therapy Unit), dressing and canister. The pump in the therapy unit delivers continuous negative pressure at -125 mmHg through tubing to a dressing placed over the incision site. Application of negative pressure wound therapy to an incision site that is closed via staples or sutures helps draw the incision edges together and remove fluid from the incision site into a canister fitted to the therapy unit. The occlusive drape of the dressing provides a negative pressure environment and protects the incision from external contamination. The systems are applied to the incision site immediately after surgery for up to seven (7) days depending on the surgeon's preference.
Indications for use [21 CFR 807.92(a)(5)]	The PREVENA PLUS Incision Management System (No Ag) (or PREVENA PLUS DUO Incision Management System (No Ag)) 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.

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

Negative Pressure Wound Therapy is the technological principal for both the subject and predicate devices

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

- The dressings are applied over the incision site in the operating room.
- The dressing is connected to the selected therapy unit (PREVENA PLUS™ 125 Therapy Unit, ACTIVAC™ Therapy Unit, V.A.C. ULTA™ Therapy Unit, or V.A.C. RX4™ Therapy Unit) via a disposable canister and, where appropriate, tubing connectors.
- The selected negative pressure therapy unit provides -125 mmHg of negative pressure continuously to the dressing for a maximum of 7 days.
- A tubing set connects the dressing to the canister to deliver negative pressure from the pump and for removal of incision fluids.
- Incision fluid is collected into the disposable canister in the therapy unit.

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

- The dressings have been modified by not adding silver to the patient/wound contacting interface layer (wicking interface layer)

- Incorporation of the SENSAT.R.A.C. Pad Tubing set associated modifications are,
    - SENSAT.R.A.C. Pad Tubing set has replaced the PREVENA Tubing set and PREVENA V.A.C. Connector

• V.A.C. Y-Connector has replaced the PREVENA Y-Connector, a system component of the PREVENA PLUS DUO Incision Management Systems (No Ag)
Performance Data [21 CFR 807.92(b)]
Summary of tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]
The PREVENA PLUS Incision Management System (No Ag) and PREVENA PLUS DUO Incision Management Systems (No Ag) were evaluated to assure safety, efficacy, conformance to design specifications and equivalence to the predicate device. The following tests were conducted: • System Performance Testing • Biocompatibility testing in accordance with ISO 10993-1 • Material specification equivalency testing with respect to Horizontal Wicking performance
Conclusions drawn [21 CFR 807.92(b)(3)]
The PREVENA PLUS Incision Management System (No Ag) and PREVENA PLUS DUO Incision Managements Systems (No Ag) are substantially equivalent to the predicate device systems with respect to indications for use and technology.