March 9, 2018

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

Re: K173426
Trade/Device Name: PREVENA PLUS Incision Management System, PREVENA PLUS DUO Incision Management System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 26, 2018
Received: January 29, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
PREVENA PLUS Incision Management System

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.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
The PREVENA PLUS DUO Incision Management System

Indications for Use *(Describe)*
The PREVENA PLUS DUO 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)

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510(k) SUMMARY

PREVENA PLUS Incision Management System
PREVENA PLUS DUO Incision Management System

Submitter Information [21 CFR 807.92(a)(1)]	
Name	KCI USA, Inc.
Address	6203 Farinon Drive San Antonio, TX 78249
Phone number	210-255-6481
Fax number	210-255-6727
Establishment Registration Number	3005178245
Name of contact person	Margaret Marsh
Date prepared	March 6, 2018
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	PREVENA PLUS Incision Management System PREVENA PLUS DUO Incision Management System
Common or usual name	Negative Pressure Wound Therapy System
Classification name	Negative Pressure Wound Therapy Powered Suction Pump
Classification panel	General and Plastic Surgery
Regulation	21 CFR 878.4780
Regulatory Class	II
Product Code(s)	OMP
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	Predicate 510(k) Numbers: • K153199 • K161897
Device description [21 CFR 807.92(a)(4)]	The negative pressure technology for the subject device systems is the same as that for the predicate device systems. The PREVENA PLUS 125 Therapy Unit is a component of the PREVENA PLUS Incision Management System and the PREVENA PLUS DUO Incision Management System. The systems provide surgical incision management via the application of negative pressure wound therapy over an incision site that has been closed with sutures or staples. The systems are 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 pump in the therapy unit delivers continuous negative pressure at -125 mmHg through tubing to a dressing placed over the incision site. The occlusive drape over the dressing provides a negative pressure

	environment and protects the incision from external contamination. The application of negative pressure draws the incision edges together, and removes fluid from the incision site into a canister fitted into the therapy unit.
Indications for use [21 CFR 807.92(a)(5)]	• 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. • The PREVENA PLUS DUO 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.

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 device systems. 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.

At a high level, the subject device and predicate device systems 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 35 cm or
  - The *PREVENA PLUS CUSTOMIZABLE Dressing* which can be configured for non-linear incisions or linear incisions up to 90 cm in length.
- The 13 and 20 cm PREVENA *PEEL & PLACE* Dressings are available in a Y configuration in the PREVENA PLUS DUO Incision Management System.
- A disposable negative pressure pump (therapy unit) provides -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 visual and audible alarms that indicate when negative pressure wound therapy may be compromised (e.g., alarms indicating an air leak in the system or when there is a blockage in the tubing, when the canister is full or missing, when the battery needs to be recharged, or in the case of a system fault.)
- The therapy unit interface provides access to therapy via an On/Off button. It also provides alarm indicators, alarm mute button, power and battery indicators, as well as a therapy life indicator.
- The intended use and instructions for use are identical.

The following design differences exist between the subject and predicate device systems:

- Internal components of the therapy unit, such as the pump, battery, board and sensors have been updated to address obsolescence and manufacturability issues.
- The external power supply has also been updated.

- A longer PREVENA PEEL & PLACE Dressing - 35 cm is now available.
- The PREVENA PLUS 125 Therapy Unit is now available in a stand-alone configuration, packaged only with Instructions for Use and a sterile canister.

Performance Data [21 CFR 807.92(b)]

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

- Bench testing demonstrated that the PREVENA PLUS 125 Therapy Unit is able to deliver continuous negative pressure at 125 mmHg within specifications under worst case conditions of air leak rate and fluid input during a 7 day test. Alarms for blockage, leakage and full canister were tested with both the PREVENA PLUS and the PREVENA PLUS DUO Systems and met specifications.
- Electrical safety and electromechanical emissions testing confirm that the subject therapy unit meets the following standards:
  - ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)
  - IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests.
  - IEC 60601-6 Edition 3.1 2013-10 – Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability
  - IEC 60601-1-8 Edition 2.1 2012-11 Medical Electrical Equipment - Part 1-8: General Requirements for Basic Safety and Essential Performance - Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems In Medical Electrical Equipment and Medical Electrical Systems
  - IEC 60601-1-11 Edition 2.0 2015-01 - Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- The new lithium battery has been verified to meet IEC 62133 Edition 2.0 2012-12.

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. No usability testing was required, as there has been no change to the user interface or to the Instructions for Use.

Conclusions drawn [21 CFR 807.92(b)(3)]

The PREVENA PLUS Incision Management System and the PREVENA PLUS DUO Incision Management System are substantially equivalent to the predicate device systems in terms of safety, performance and indications for use.