February 15, 2019

KCI USA, Inc.
Shannon Scott
Sr. Director, Regulatory Affairs
6203 Farinon Drive
San Antonio, Texas 78249

Re: K181507
Trade/Device Name: PREVENA RESTOR™ Incision Management System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 16, 2019
Received: January 17, 2019

Dear Shannon Scott:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Kimberly Ferlin -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181507

Device Name
PREVENA RESTOR(TM) Incision Management System

Indications for Use *(Describe)*
The PREVENA RESTOR(TM) 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."

510(k) SUMMARY

PREVENA RESTOR™ 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	210-255-7433
Fax number	210-255-6727
Establishment Registration Number	3005178245
Name of contact person	Shannon Scott
Date prepared	February 15, 2019
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	PREVENA RESTOR™ 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) Number(s): K180855 K161897 K153199
Device description [21 CFR 807.92(a)(4)]	The negative pressure technology for the subject device is the same as that for the predicate device systems. The PREVENA RESTOR™ dressing is a component of the PREVENA RESTOR™ 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 up to seven (7) days depending on the surgeon's preference. The pump in the therapy unit delivers continuous negative pressure at -125 mmHg through tubing connected to a PREVENA RESTOR™ dressing placed over the incision site. The integrated one-piece dressing, which includes an occlusive film, provides

510(k) SUMMARY

PREVENA RESTOR™ Incision Management System

	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 to the therapy unit.
Indications for use [21 CFR 807.92(a)(5)]	The PREVENA RESTOR™ 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 devices. 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 film 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:

- Both device systems contain the same Indications for Use.
- The choice of therapy unit has not changed from the predicate systems.
- The dressing is connected to the PREVENA PLUS™ 125 Therapy Unit, ACTIV.A.C.™ Therapy Unit, V.A.C. ULTA™ Therapy Unit, or V.A.C. RX4™ Therapy Unit via a disposable canister and appropriate tubing connections.
- The dressings are constructed from the same materials and are sterilized in the same type of packaging.
- The dressings are applied over the same types of incisions on the same anatomical locations.

The following design difference exists between the subject and predicate device:

- The PREVENA RESTOR™ dressings include precision designed pre-cut foam.
- The PREVENA RESTOR™ dressing are presented in various shapes and sizes.

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 subject PREVENA RESTOR™ dressing is substantially equivalent to the predicate in the delivery of continuous negative pressure at -125 mmHg within specifications under worst-case conditions of air leak rate and fluid input over the intended duration of use.

510(k) SUMMARY

PREVENA RESTOR™ Incision Management System

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 only minor changes to the user interface and to the Instructions for Use.
Conclusions drawn [21 CFR 807.92(b)(3)]
The subject PREVENA RESTOR™ Incision Management System and its identified predicate are substantially equivalent in terms of basal design, utilized materials, principles of operation, mode-of-action, safety, performance, type of packaging, and indications for use.