DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 4, 2016

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

Re: K161897
Trade/Device Name: Prevena Duo, Prevena Plus Duo Incision Management Systems With Peel & Place Dressings
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: July 7, 2016
Received: July 11, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*
K161897

Device Name
PREVENA DUO Incision Management System
PREVENA PLUS DUO Incision Management System

Indications for Use *(Describe)*
The PREVENA 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

PREVENA DUO™ Incision Management System with PEEL & PLACE™ Dressings
and
PREVENA PLUS DUO™ Incision Management System with PEEL & PLACE™ Dressings

Submitter Information [21 CFR 807.929(a)(1)]	
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive San Antonio, TX 78249
Phone number	210-255-6481
Fax number	210-255-6727
Establishment Registration Number	3009897021
Name of contact person	Margaret Marsh, Technical Director Regulatory Affairs
Date prepared	September 19, 2016
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	• ***PREVENA DUO™ Incision Management System with PEEL & PLACE™ Dressings*** • ***PREVENA PLUS DUO™ Incision Management System with PEEL & PLACE™ Dressings***
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 Incision Management System***, cleared recently under 510(k) K141017 • ***PREVENA PLUS Incision Management System***, cleared recently under 510(k) K153199
Device description [21 CFR 807.92(a)(4)]	Both the ***PREVENA DUO™ Incision Management System*** (with the ***PREVENA 125 Therapy Unit)*** and the ***PREVENA PLUS DUO™ Incision Management System*** (with the ***PREVENA PLUS 125 Therapy Unit)*** are negative pressure wound therapy systems designed for the management of two surgical incisions simultaneously with one ***PREVENA Therapy Unit***. Both systems provide two ***PREVENA PEEL & PLACE Dressings*** (which can be for linear incisions up to 13 or 20 cm in length) which are connected to their respective therapy units via a new ***PREVENA Y-Connector***. Therapy is continuously applied to each incision at -125 mmHg for 2 to 7 days. Length of therapy is per surgeon preference.
Indications for use [21 CFR 807.92(a)(5)]	The ***PREVENA DUO™*** and the ***PREVENA PLUS DUO™ Incision Management Systems with PEEL & PLACE™ Dressings*** are 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 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 remove 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 devices and predicate devices are based on the following same technological elements:

- Both device systems have the same indications for use.
- The ***PEEL & PLACE™ Dressings*** are constructed from the same materials and design and are sterilized in the same packaging.
- The ***PEEL & PLACE™ Dressing*** is applied over the incision site in the operating room.
- The dressing is connected to the selected therapy unit via a disposable canister and, where appropriate, tubing connectors.
- The choice of therapy unit has not changed from the predicate systems. The selected negative pressure therapy unit provides -125 mmHg of negative pressure continuously to the dressing for a maximum of 7 days.
- Incision fluid is collected into the disposable canister in the therapy unit.
- The therapy unit provides alarms that indicate when negative pressure wound therapy may be compromised (e.g., visual and audible alarms indicating an air leak in the system, or when the canister is full or batteries are low).

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

- Two ***PEEL & PLACE™ Dressings*** and a new ***PREVENA Y-Connector*** are provided in each ***PREVENA DUO™*** system box to allow for simultaneous use over two incisions with one therapy unit.
- System choices include two 13 cm dressings, one 13 and 20 cm dressing or two 20 cm dressings per system box.
- The 13 cm ***PEEL & PLACE™ Dressing***, while identical in materials and design to the predicate 20 cm ***PEEL & PLACE™ Dressing***, is shorter in length to provide for use on incisions up to 13 cm in length. (The 20 cm ***PEEL & PLACE™ DRESSING*** is designed for use on incisions up to 20 cm in length.)

Performance Data [21 CFR 807.92(b)]

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

- Negative pressure performance testing indicates that the ***PREVENA DUO*** and ***PREVENA PLUS DUO Incision Management Systems*** are able to provide negative pressure within specification to each dressing over a 7 day use test and under test conditions of maximum air leak and simulated wound fluid input. Testing also confirms delivery of appropriate therapy unit alarms.
- Human factors engineering assessment indicates that these use of these new systems does not create new critical usability tasks and that a new usability study is not required.

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.

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

The ***PREVENA DUO™ Incision Management System with PEEL & PLACE™ Dressings*** and the ***PREVENA PLUS DUO™ Incision Management System with PEEL & PLACE™ Dressings*** are substantially equivalent to their predicates in terms of safety, function and indications for use.