



April 19, 2019

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

Re: DEN180013

Trade/Device Name: PREVENA 125 and PREVENA PLUS 125 Therapy Units

Regulation Number: 21 CFR 878.4783

Regulation Name: Negative pressure wound therapy device for reduction of wound complications

Regulatory Class: Class II

Product Code: QFC

Dated: March 14, 2018

Received: March 15, 2018

Dear Shannon Scott:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the PREVENA 125 and PREVENA PLUS 125 Therapy Units, a prescription device under 21 CFR Part 801.109 with the following indications for use:

PREVENA 125 and PREVENA PLUS 125 Therapy Units manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, PREVENA 125 and PREVENA PLUS 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the PREVENA 125 and PREVENA PLUS 125 Therapy Units, and substantially equivalent devices of this generic type, into Class II under the generic name negative pressure wound therapy device for reduction of wound complications.

FDA identifies this generic type of device as:

Negative pressure wound therapy device for reduction of wound complications. A negative pressure wound therapy device for reduction of wound complications is a powered suction pump intended for wound management and reduction of wound complications via application of negative pressure to the wound, which removes fluids, including wound exudate, irrigation fluids, and infectious materials. This device type is intended for use with wound dressings classified under 21 CFR 878.4780. This classification does not include devices intended for organ space wounds.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 15, 2018, FDA received your De Novo requesting classification of the PREVENA 125 and PREVENA PLUS 125 Therapy Units. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the PREVENA 125 and PREVENA PLUS 125 Therapy Units into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the PREVENA 125 and PREVENA PLUS 125 Therapy Units can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 7. Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Shelf life testing Labeling
Electrical shock or electromagnetic interference with other devices	Electromagnetic compatibility testing Electrical safety testing Labeling
Damage to underlying tissue (e.g., wound maceration, uncontrolled bleeding) due to <ul style="list-style-type: none"> • Mechanical failure • Software malfunction • Use error 	Clinical data Non-clinical performance testing Usability testing Shelf life testing Software verification, validation, and hazard analysis Labeling
Increase in wound complications due to use error	Clinical data Usability testing Labeling

In combination with the general controls of the FD&C Act, the negative pressure wound therapy device for reduction of wound complications is subject to the following special controls:

- (1) Clinical data must demonstrate that the device performs as intended under anticipated conditions of use and evaluate the following:
 - (a) Wound complication rates; and
 - (b) All adverse events.
- (2) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (3) Performance data must demonstrate the sterility of the patient-contacting components of the device.
- (4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.
- (5) Usability testing must demonstrate that intended users can correctly use the device, based solely on reading the instructions for use.
- (6) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested in a worst-case scenario for the intended use life:
 - (a) Ability to maintain pressure levels at the wound site under a worst-case scenario for the intended use life;
 - (b) Fluid removal rate consistent with the wound types specified in the indications for use; and
 - (c) Timely triggering of all alarms.
- (7) Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of the device.
- (8) Software verification, validation, and hazard analysis must be performed.
- (9) Labeling must include the following:
 - (a) Instructions for use;
 - (b) A summary of the device technical specifications, including pressure settings, modes (e.g., continuous or intermittent), alarms, and safety features;
 - (c) Compatible components and devices;
 - (d) A summary of the clinical evidence for the indications for use;
 - (e) A shelf life for sterile components; and
 - (f) Use life and intended use environments.
- (10) For devices intended for use outside of a healthcare facility, patient labeling must include the following:
 - (a) Information on how to operate the device and its components and the typical course of treatment;
 - (b) Information on when to contact a healthcare professional; and
 - (c) Use life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the negative pressure wound therapy device for reduction of wound complications they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Frances Wilder at 240-402-3999.

Sincerely,

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health