July 1, 2022

3M Health Care Business Group
Teri Feeley
Sr. Regulatory Affairs Associate
6203 Farinon Dr.
San Antonio, Texas 78249

Re: K220660
Trade/Device Name: Prevena™ Restor™ Adapti-Form™ Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: March 4, 2022
Received: March 7, 2022

Dear Teri Feeley:

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,

Julie Morabito, PhD
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220660

Device Name
Prevena™ Restor™ Adapti-Form™ Dressing

Indications for Use *(Describe)*
The Prevena™ Restor™ Adapti-Form™ Dressing is part of the Prevena™ Restor™ Incision Management System and 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™ Restor™ Adapti-Form™ Dressing

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Date Prepared: 25 Feb 2022

Name of Subject Device: Prevena™ Restor™ Adapti-Form™ Dressing
Predicate Device: Prevena™ Restor™ Incision Management System (K181507)
Reference Device: Prevena Plus Incision Management System (Prevena Customizable Dressing components of system) (K153199)
Common or Usual Name: Dressing component of Prevena Incision Management System
Classification Name: Negative Pressure Wound Therapy Powered Suction Pump (and components)
Regulation Number: 21 CFR 878.4780
Regulatory Class: Class II
Product Code: OMP

Device Description

The Prevena Restor™ Incision Management System consist of the following components for use together as a system:

- Prevena Plus Therapy Unit & canister
- Prevena Restor Adapti-Form Dressing:
  - Foam Dressing with a skin interface layer
  - V.A.C. Drape
  - SensaT.R.A.C. Pad
  - Hydrocolloid Sealing strips

The Prevena™ Restor™ Adapti-Form™ Dressing is designed to be compatible for use with previously cleared V.A.C. Negative Pressure Wound Therapy (NPWT) Units:

- ActiV.A.C. Therapy Unit,
- V.A.C. ULTA Therapy Unit, and
- V.A.C. Rx4 Therapy Unit.

510(k) Summary
Prevena™ Restor™ Adapti-Form™ Dressing

Intended Use / Indications for Use

The Prevena Restor Adapti-Form Dressing is part of the Prevena Restor Incision Management System and 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.

Summary of Technological Characteristics

The Prevena™ Restor™ Adapti-Form™ Dressing is a customizable dressing, designed for use over linear, non-linear, intersecting incisions. The dressings are for use over various anatomical locations as determined at the discretion of the healthcare provider. The dressing is intended to be used with the Prevena Plus™ Therapy Unit or compatible V.A.C. Therapy Unit to achieve its intended purpose as the Prevena Restor Incision Management system.

The subject device indications for use, technological characteristics and principles of operation are substantially equivalent to the predicate. The difference between the subject and predicate device is the subject device dressing components are provided separately to offer the ability to cut/customize the dressing to address application needs that may not be met with the predicate (Prevena Restor Dressing, K181507)).

A table comparing the key features of the subject and predicate devices is provided below.

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]		
Characteristic	**Subject Device:**	**Predicate Device:** Prevena Restor Incision Management System K181507 **Reference Device:** Prevena Plus Incision Management system with Prevena Customizable Dressing, K153199
Intended Use	Identical to predicate	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.
Indicated Wound Types	Identical to predicate	• Surgically closed incisions
V.A.C. Negative Pressure Wound Therapy Units	Identical to predicate	• Prevena Plus Therapy Unit 7 day • Prevena Plus Therapy Unit 14-day • ACTIV.A.C.™ Therapy Unit* • V.A.C.ULTA™ Therapy Unit* • V.A.C.RX4™ Therapy Unit*

		*and associated canisters
Use environment/Care Setting of dressing kit	Identical to predicate	The Dressing will be initially applied in the operating room/surgery center and then may transition home with the patient
Dressing Components	Identical to reference device	1) Foam dressing with skin interface layer 2) Hydrocolloid sealing strips 3) Adhesive drape 4) Tubing with interface pad
Sterilization Method & SAL	Identical to predicate	Gamma radiation 10^{-6}

Performance Data

Summary of non-clinical tests conducted for determination of substantial equivalence:

- Prevena Restor Incision Management System negative pressure test
- Package Integrity/Stability testing was done in accordance with ISO 11607-1
- Product performance stability testing of dressing components after sterilization
- Human factors evaluation
- Biocompatibility testing to ISO 10993-1

In all instances, the Prevena™ Restor™ Adapti-Form™ Dressing which is a part of the Prevena™ Restor™ Incision Management System functioned as intended and all test results passed.

Clinical and Pre-clinical testing were not necessary to demonstrate substantial equivalence.

Conclusions

The subject device's Intended Use, indications for use, fundamental technology and principles of operation are unchanged compared to the predicate and reference devices cleared under K181507 & K153199.

The performance data demonstrates that the Prevena Restor Adapti-Form Dressing is substantially equivalent to the predicate product in terms of safety and effectiveness.