June 4, 2021

Cardinal Health
℅ Jillian Connery
Principal Specialist Regulatory Affairs
Patient Recovery, Cardinal Health
777 West Street
Mansfield, Massachusetts 02048

Re: K202217
Trade/Device Name: Kendall™ NPWT Incision Management Device
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 5, 2021
Received: May 7, 2021

Dear Jillian Connery:

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,

for Lixin Liu, Ph.D.
Acting 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)*
K202217

Device Name
Kendall™ Negative Pressure Wound Therapy Incision Management Device

Indications for Use *(Describe)*
The Kendall™ Negative Pressure Wound Therapy (NPWT) Incision Management Device, when used with a Kendall™ NPWT Incision Management Dressing Kit, 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 system is intended for use in acute, extended and home care settings.

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.

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Section 5
510(k) Summary

1. 510(k) Owner:

Cardinal Health
3651 Birchwood Drive
Waukegan, IL 60085

Contact: Christine Kuntz Nassif/ Jillian Connery
Title: RA Manager/ Principal RA Specialist
777 West Street
Mansfield, MA 02048
Telephone: (508) 618-3756/ (614) 270-8991

Date Prepared: June 3, 2021

2. Device:

Trade Name: Kendall™ NPWT Incision Management Device
Common Name: Negative Pressure Wound Therapy Powered Suction Pump
Classification Panel: General & Plastic Surgery
Regulation Number: 21 CFR 878.4780
Product Code: OMP
Classification: Class II

3. Predicate Devices:

PREVENA PLUS DUO Incision Management System (K180855)

4. Device Description:

The Kendall™ Negative Pressure Wound Therapy (NPWT) Incision Management (IM) Device is a portable, single use, battery operated (lithium AA) suction pump with a canister. The device, when connected to a Kendall™ NPWT Incision Management Dressing Kit, applies negative pressure to an incision site that is closed with sutures or staples. The device can be set at negative pressures of -50mmHg to -125mmHg in 5mmHg increments. The device will stop working after 7 days and cannot be restarted. Visual and audible alerts from the device alerts the user to possible leaks, blockages, a full canister, low batteries, and therapy time out.

5. Indications for Use:

The Kendall™ Negative Pressure Wound Therapy (NPWT) Incision Management Device, when used with a Kendall™ NPWT Incision Management Dressing Kit, 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 system is intended for use in acute, extended and home care settings.

6. Technological Characteristics Comparison:

Feature	Kendall™ NPWT Incision Management Device	PREVENA PLUS DUO Incision Management System (K180855)
Indications for Use	The Kendall™ Negative Pressure Wound Therapy (NPWT) Incision Management Device, when used with a Kendall™ NPWT Incision Management Dressing Kit, 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 system is intended for use in acute, extended and home care settings.	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.
Product Code	OMP	OMP
Patient Population	Adult single patient	Adult single patient
Environment of Use	Hospitals, Clinics, Long Term Care and Home Care settings	Not specified
Dressing Kit	Kendall™ NPWT IM Dressing Kit	Prevena Plus Peel & Place Dressing, Prevena Plus Customizable Dressing
Weight	0.43 lbs.	0.64 lbs.
Pressure Range	- 50mmHg to -125mmHg using 5mmHg increments	-125mmHg
Pressure Sensing	Same as predicate	Wound bed
Canister Volume	50 mL	150 mL
Operator Interface	On/Off Button, Up/Down Buttons	On/Off Button, Alert Mute Button
Power Source	2 AA non-rechargeable lithium Batteries	Rechargeable battery
Useful Life	Up to 7 days	Up to 14 days*
Alerts/Alarms	Visual and audible alerts to indicate air leak, blockage, canister full, low battery	Visual and audible alarms to indicate air leak, blockage, canister full/missing, low battery,

		system fault
Therapy Time Indicator	Yes	Yes
Sterilization	Non-sterile	Non-sterile

*-Note, Prevena Plus dressing is indicated to be changed after 7 days.

At a high level, the Kendall™ NPWT Incision Management Device and the predicate device are based on the following same technological elements:

- Indications for Use
- Patient Population
- Dressing Kit (both indicated for up to 7 days)
- Use of a multi-lumen tubing for identification of blockages
- Negative pressure measurement at wound site
- Canister to hold removed exudate
- Visual and audible alerts to indicate air leak, blockage, canister full, low battery
- Therapy life indicator

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

- Prevena Plus is used with the Prevena Plus Peel & Place or the Prevena Plus Customizable Dressing, the Kendall™ NPWT IM Dressing is used with the Kendall NPWT Incision Management Device. The predicate device has been tested to different dressings; whereas the subject device has been tested to the Kendall™ NPWT IM Dressing Kit and is indicated for use with only the Kendall™ NPWT IM Dressing Kit.
- Prevena Plus disposable negative pressure pump is cleared for up to 14-day use, however the dressing is indicated to be replaced after 7 days. The Kendall™ NPWT IM Dressing Kit can be used for up to 7 days. The Instructions for Use specify a maximum use of 7 days at which time, the pump will be permanently disabled. The subject device has been tested to the 7 day use.
- Prevena Plus is set at -125mmHg. Kendall™ NPWT IM Device can be set at negative pressures of -50mmHg to -125mmHg in 5mmHg increments. The pressure tests were done at both extremes of the pressure range to verify effectiveness.
- Prevena Plus has a larger canister volume (150 mL) as compared to Kendall™ NPWT IM Device with 50 mL. The Prevena Plus has a larger canister as it is indicated for a longer use time. The canister for the subject device may be replaced and the user is instructed on how to do so.
- Prevena Plus weighs slightly more than the Kendall™ NPWT IM Device. The minor weight difference should not affect the user operating the device.
- Prevena Plus has a rechargeable battery. Kendall™ NPWT IM Device uses 2 AA lithium batteries. The batteries supplied with the device are lithium, but can be replaced with other AA batteries, if required. The lithium batteries supplied are in conformance with IEC 62133: 2012; however, the user is instructed how to change

batteries if needed. The user is recommended to use lithium batteries for best performance.

These differences are not critical to the intended use of the device. When the Kendall™ NPWT Incision Management Device is used as indicated with the Kendall™ NPWT Incision Management Dressing Kit, these differences do not raise different questions of safety and effectiveness and are not critical to the intended use.

7. Performance Data:

Sterilization and Shelf Life

The Kendall™ NPWT IM Device, Canister and carry case are provided non-sterile. The Kendall™ NPWT IM Device is packaged with the Kendall™ NPWT IM Dressing Kit, which includes a 3 year expiration date. For this reason, the package labels include a three-year shelf life.

Biocompatibility Testing

The Kendall™ NPWT Incision Management Device is categorized as surface contacting device on intact skin for a contact duration defined as prolonged (between 24 hours and 30 days). Sensitization, Irritation and Cytotoxicity complies with ISO 10993-1 and FDA Guidance "Use of International Standard ISO 10993 – Part 1: Evaluation and testing within a risk management process".

Software

The software documentation in this submission has been assembled according to the recommendations in the FDA document, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The software Level of Concern has been evaluated and determined to be Moderate, and appropriate documentation included in the submission.

Electromagnetic Compatibility and Electrical Safety

The Kendall™ NPWT Incision Management Device complies with the following standards:

- ANSI/AAMI ES 60601-1: 2005/(R)2012 and A1: 2012, C1: 2009/(R)2012 and A2: 2010/(R)2012
- IEC 60601-1-2: 2014
- IEC 60601-1-6: 2010 + A1: 2013
- IEC 60601-1-11: 2015
- ISO 10993-5: 2009
- ISO 10993-10: 2010
- ANSI/AAMI HE 75: 2009/(R)2018

- IEC 62366-1: 2015 + CORRIGENDIUM 1 (2016)

Non-Clinical Testing

The following performance data were provided in support the conclusion that the proposed device is substantially equivalent to the predicate device.

Bench Testing
The following testing has been conducted to support the conclusion that the proposed device is substantially equivalent to the predicate device:

- Pressure Test verifies the ability to maintain expected pressure at the wound site, based on an acceptable pressure between -50 and -125mmHg in 5mmHg increments and that the device is capable of measuring the pressure at the wound site comparable to the predicate device.
- Occlusion Detection Test verifies the device would alert in the presence of a blockage condition (i.e. blocked tubing). This alerts the user of suboptimal therapy.
- Leak Alert Testing verifies the device would alert in the presence of a leak condition (i.e. improperly sealed dressing). This alerts the user of suboptimal therapy.
- Full Canister Alert Testing verifies the device would alert in the presence of a full canister. This alerts the user of suboptimal therapy.
- Device Multi-orientation Test verifies the canister did not leak and the subject device is functional in a series of orientations that could be expected.
- Battery Alert Test verifies the device would alert in the presence of a low battery condition. This alerts the user to change batteries to avoid suboptimal therapy.
- Design Validation Testing validates the performance when in a simulated use scenario, running the device for 7 days with pseudo-exudate.

There were no Human Clinical or Animal Performance Studies required for substantial equivalence determination.

Usability Testing
Usability Testing was performed per ISO 62366-1 and ANSI/AAMI HE 75. Testing was performed using lay users who represent patients and lay caregivers to support the use of the device in the home environment and with clinicians to support the use of the device in the hospital.

8. Conclusion:

The performance data demonstrate that the proposed Kendall™ NPWT Incision Management Device functions as intended and is considered substantially equivalent to the predicate device.