July 31, 2020

Cardinal Health
Christine Kuntz-Nassif
Regulatory Affairs Manager
777 West Street
Mansfield, MA 02048

Re: K191101
Trade/Device Name: Kendall NPWT Incision Management Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: June 29, 2020
Received: July 1, 2020

Dear Christine Kuntz-Nassif:

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,

Anjana Jain, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191101

Device Name
Kendall NPWT Incision Management Dressing Kit

Indications for Use *(Describe)*
The Kendall NPWT Incision Management Dressing Kit, when used with a Cardinal Health NPWT CATALYST, ALLY or ALLY TO GO Devices, 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 Cardinal Health NPWT CATALYST, ALLY, or ALLY TO GO 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.

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510(k) Summary

1. 510(k) Owner:

Cardinal Health
3651 Birchwood Drive
Waukegan, IL 60085
Telephone: (954) 585-5145

Contact: Christine Kuntz-Nassif
Title: Regulatory Affairs Manager
Date Prepared: July 31, 2020

2. Device:

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

3. Predicate Devices:

Prevena Plus Incision Management System (K180855)

4. Device Description:

The Kendall Negative Pressure Wound Therapy Incision Management Dressing Kit is a wound dressing kit to be used with cleared Cardinal Health Negative Pressure Wound Therapy (NPWT) CATALYST, ALLY, and ALLY to GO systems (K171499).

The disposable single-use sterile Kendall NPWT Incision Management Dressing Kit consists of five dressing configurations, tubing, and drape strips. The dressing covers the closed surgical site and forms a seal over the sutured or stapled surgical site. The proximal end of the tubing is attached to the dressing while the distal end of the tubing attaches to an exudate canister. The powered suction pump delivers negative pressure to the dressing to aid in the removal of exudate from the wound into the exudate canister. The drape strips are used to patch any air leaks if necessary.

5. Indications for Use:

The Kendall NPWT Incision Management Dressing Kit, when used with Cardinal Health NPWT CATALYST, ALLY, and ALLY TO GO Devices, 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 Cardinal Health NPWT CATALYST, ALLY, or ALLY TO GO System is intended for use in acute, extended and home care settings.

6. Technological Characteristics Comparison

Table of Comparison to Predicate Device

Elements of Comparison	Proposed Device Kendall NPWT Incision Management Dressing Kit	Predicate Device Prevena Plus Incision Management System
Indications for Use	The Kendall NPWT Incision Management Dressing Kit, when used with a Cardinal Health CATALYST, ALLY or ALLY TO GO NPWT Devices, 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 Cardinal Health NPWT CATALYST, ALLY, or ALLY TO GO System is intended for use in acute, extended and home care settings.	The Prevena Plus 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	Adult
Environment of Use	Hospitals, Clinics, Long Term Care and Home Care settings	Hospitals, Clinics, Long Term Care and Home Care settings
Reusable	Single use only	Single use only
Sterilization	EtO	EtO
Dressing Kit Components	• Layered dressing containing a film drape, foam and contact underlayer that wicks fluid away from the surface of the incision • Dual lumen polyvinyl urethane tubing with SpeedConnect to connect to dressing and Twist 'N Connect ABS exudate canister connector • Drape strips	• Layered dressing containing a film drape, foam and contact underlayer containing Iconic Silver that wicks fluid away from the surface of the incision • Tubing with SENSAT.R.A.C to connect to dressing and exudate canister connector • Patch/Sealing strips, drapes
Dressing Sizes	• 10 x 20 cm • 10 x 41 cm • 15 x 20 cm • 10 x 30.5 cm • 15 x 30.5 cm	• 35 cm Peel and Place • 20 cm Peel and Place • 13 cm Peel and Place • Customizable
Compatible NPWT Devices	• CATALYST • ALLY • ALLY TO GO	• Prevena Plus
Negative Pressure at Wound Site	• ALLY/ALLY TO GO: -50, -75, -100, -125, -150mmHg • CATALYST: -70, -120, -150mmHg	• -125mmHg
Use Life of Dressing	7 days maximum	14 days maximum

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

- Indications for Use
- Environment of Use
- Patient Population
- Use of drape/sealing strips to patch potential leaks in the dressing
- Use of a multi-lumen tubing for identification of blockages
- Connections at proximal end to dressing and distal end to exudate canister
- Layered dressing containing foam and non-stick contact layer
- Single use only

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

- Prevena skin interface layer contains silver to reduce microbial colonization in the fabric, Kendall NPWT Incision Management Dressing does not contain silver
- Prevena dressing kit is used at -125mmHg. Kendall NPWT Incision Management Dressing Kit can be used at the following negative pressures: -50mmHg, -75mmHg, -100mmHg, -125mmHg and -150mmHg with the ALLY/ALLY TO GO and -70mmHg, -120mmHg and -150mmHg with the CATALYST.

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

7. Performance Data

Biocompatibility Testing:

The biocompatibility of the Kendall NPWT Incision Management Dressing Kit has been demonstrated through testing per ISO 10993-1 to support limited contact exposure (≥24 hours to <30 days) on a breached or compromised surface. The biocompatibility testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Subacute/Subchronic Toxicity
- 4 Week Full Thickness Wound Healing in Rats

Non-Clinical Testing

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

- Absorbency to demonstrate that the proposed incision management dressing can; in the absence of negative pressure absorb wound exudate.
- Alert Testing to demonstrate that the Kendall NPWT Incision Management Dressing Kit does not inhibit the NPWT CATALYST/ALLY Systems from detecting and producing an alert of leaks, or occlusion detection/canister full.
- Useful Life Testing to confirm the proposed Kendall NPWT Incision Management Dressing Kit can maintain target pressure and transport a simulated exudate away from the wound site into a fluid collection canister over the useful life of the dressing comparable to the predicate device.

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

8. Conclusion:

The performance data demonstrate that the proposed Kendall NPWT Incision Management Dressing Kits function as intended and are considered substantially equivalent to the predicate device and does not raise different questions of safety and effectiveness.