September 22, 2017

Cardinal Health
Beth Foster
Regulatory Affairs Manager
1500 S Waukegan Rd
Waukegan, Illinois 60085

Re: K171499
Trade/Device Name: Occlusion Detection Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: August 29, 2017
Received: August 30, 2017

Dear Beth Foster:

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 (DICE) 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 (DICE) 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
**510(k) Number (if known)**
K171499

**Device Name**
Cardinal Health NPWT Occlusion Detection Dressing Kit and Canister

**Indications for Use (Describe)**
The Cardinal Health NPWT device is an integrated wound management system, indicated for the application of continual or intermittent negative pressure wound therapy. The system may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials. The system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The system is intended for use in acute, extended and home care settings.

**Type of Use (Select one or both, as applicable)**
- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health NPWT Occlusion Detection Dressing Set and Canister
(A summary of safety and effectiveness information in accordance with the requirements of 21 CFR 807.92)

510(k) Number: K171499

Applicant: Cardinal Health
1500 S Waukegan Road
Waukegan, IL 60085

Establishment Registration Number: 3006367520
Regulatory Affairs Contact: Beth Foster
Telephone: 954-585-5145
Fax: N/A
E-mail: beth.foster@cardinalhealth.com

Date Summary Prepared: May 22, 2017

Trade Name: Cardinal Health NPWT Occlusion Detection Dressing Kit and Canister
Common Name: Negative Pressure Wound Therapy Dressing Kit and Canister
Classification Name: Powered Suction Pump (21 CFR 878.4780)
Classification Panel: General & Plastic Surgery
Regulatory Class: Class II
Product Code(s): OMP

Legally marketed device(s) to which equivalence is claimed: K150124 Cardinal Health NPWT PRO HC

Reason for 510(k) Submission: Modification of the tubing and fluid canister to allow detection of blockage or an occlusion that may occur in the dressing or within the tubing, which in turn triggers an alarm on the pump.

Device Description: The Cardinal Health NPWT system consists of a powered suction pump device that provides continuous or intermittent negative pressure (SVED – K142916, PRO/PRO to GO/PRO at HOME – K143016, PRO HC – K150124) with a built-in placement holder for the fluid collection canister, various sizes and shapes of polyurethane foam dressing, canister tubing with clamps and connectors, polyurethane drape with adhesive, and fluid collection
canisters. The pump devices are AC-powered, portable suction devices with battery backup that provide localized negative pressure to remove fluids and infectious materials from the wound. The devices must be used with the Cardinal Health NPWT dressing kits, which are available in various foam sizes. Each Cardinal Health NPWT dressing kit contains an occlusion detection tubing set, various sizes of polyurethane foam, and a polyurethane drape with adhesive.

The purpose of this submission is to modify 1) the tubing in the dressing kits and 2) the disposable fluid collection canister to allow detection of blockage or an occlusion that may occur in the dressing or within the tubing, which in turn triggers an alarm on the pump. The modification consists of a dual lumen tubing set with a twist and lock port that attaches to a disposable fluid collection canister. The canister is modified with three ports in the cap of the canister. One port accepts the twist and lock end of the tubing set for collection of exudate from the wound, and two ports connects to sensors within the pump device. The modifications to the tubing set and the fluid collection canister cap do not require any software or hardware changes to the NPWT pump devices. There are no changes to the Indications for Use for any of the NPWT devices.

**Indications for Use:**

The Cardinal Health NPWT device is an integrated wound management system, indicated for the application of continual or intermittent negative pressure wound therapy. The system may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials. The system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The system is intended for use in acute, extended and home care settings.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Cardinal Health NPWT Dressing Kit with Occlusion Detection</th>
<th>Cardinal NPWT PRO HC Dressing Kit without Occlusion Detection K150124</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>Same as predicate</td>
<td>The Cardinal Health NPWT SVED, PRO Family and PRO HC are integrated wound management systems, indicated for the application of continual or intermittent negative pressure wound therapy to the wound as the device may promote wound healing by the removal of fluids, including</td>
</tr>
</tbody>
</table>
The system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic pressure), flaps and grafts. The system is intended for use in acute, extended and home care settings.

<table>
<thead>
<tr>
<th>Product Code</th>
<th>OMP</th>
<th>OMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Population</td>
<td>Same as predicate</td>
<td>Adult single patient</td>
</tr>
<tr>
<td>Environment of Use</td>
<td>Same as predicate</td>
<td>Hospitals, Clinics, Long Term Care and Home Care settings</td>
</tr>
<tr>
<td>Used in conjunction with Cardinal Health NPWT pump devices</td>
<td>Same as predicate</td>
<td>Yes</td>
</tr>
<tr>
<td>Alarms</td>
<td>Low Pressure/Leak, Canister Full/Blockage, Low Battery</td>
<td>Low Pressure/Leak, Canister Full, Low Battery</td>
</tr>
<tr>
<td>Drape</td>
<td>Same as predicate</td>
<td>Polyurethane film with gentle acrylic adhesive</td>
</tr>
<tr>
<td>Foam Dressings</td>
<td>Same as predicate</td>
<td>• Black foam (Polyurethane), Hydrophobic, Open pore structure (400-600 microns) with multiple foam sizes: Sm: 10x8x3 cm Med: 20x12.5x3cm Lg: 25x15x3cm XLg: 58.5x33x3cm • White foam hydrophilic, high density, smaller pore size, flexible wet or dry • Black foam (Polyurethane), Hydrophobic, Open pore structure (600-900 microns) Strips ~25x3.8 x1.3 cm</td>
</tr>
<tr>
<td>Tubing</td>
<td>Polyurethane tubing with ABS plastic port, Dual lumen tubing with SpeedConnect, Twist and lock port for attachment to canister</td>
<td>Polyvinyl chloride tubing with French connect port, Single lumen tubing with SpeedConnect, French connect port to attach for attachment to canister</td>
</tr>
<tr>
<td>Canister</td>
<td>Twist and lock port for attachment to tubing, Porous hydrophobic filter to prevent fluid ingress, 300cc and 500cc canister volume</td>
<td>Grommet port for attachment to tubing, Porous hydrophobic filter to prevent fluid ingress, 300cc and 500cc canister volume</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Non-cytotoxic, Non-sensitizing, Non-irritating</td>
<td>Non-cytotoxic, Non-sensitizing, Non-irritating</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Same as predicate</td>
<td>EtO Sterilization</td>
</tr>
<tr>
<td>Shelf Life of Dressing Set</td>
<td>90 days</td>
<td>3 years</td>
</tr>
</tbody>
</table>

**Performance Data**

The following performance data were provided in support of the substantial equivalence determination. There were no Clinical or
Animal Performance Studies required for substantial equivalence determination.

**Bench Testing**
The following testing has been conducted to verify that the modifications of the Dressing Kit and Canister, allowing the detection of a blockage or occlusion, will perform as intended with the Cardinal Health NPWT devices:

- Proper functioning of device features and alarms
- Pressure stability testing
- Exudate removal testing
- Usability testing

**Conclusions**
The performance data demonstrate that the modifications to the NPWT Dressing Kit and Canister function as intended with no change in safety or effectiveness of the system and are considered substantially equivalent to the predicate device.