DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 2, 2015

Cardinal Health
% Ms. Allison Scott
Navigant Consulting Incorporated
9001 Wesleyan Road, Suite 200
Indianapolis, Indiana 46268

Re: K150124
Trade/Device Name: Cardinal Health NPWT PRO HC System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: August 6, 2015
Received: August 7, 2015

Dear Ms. Scott:

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 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" (21CFR 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 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 yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Cardinal Health NPWT PRO HC System

Indications for Use *(Describe)*
The Cardinal Health NPWT PRO HC system is an integrated wound management system, 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 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)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) Summary

I. Submitter Information

Cardinal Health
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Waukegan, IL 60085

Contact Person: Judith Harbour, RAC
954-582-7433
Judith.Harbour@cardinalhealth.com

Date Prepared: July 14, 2015

II. Device Information

Name of Device:	Cardinal Health NPWT PRO HC
Common Name:	Negative Pressure Wound Therapy Powered Suction Pump
Classification Name(s):	Powered Suction Pump (21 CFR 878.4780)
Regulatory Class:	II
Product Code:	OMP

III. Predicate Device

Primary: K143016 Cardinal Health NPWT PRO Family
This predicate has not been subject to a design-related recall.

Reference: K093564 Innovative Therapies, Inc. Sved® Wound Treatment System
K111333 Innovative Therapies, Inc. Antlia III Wound Treatment System

4. Device Description

The Cardinal Health NPWT PRO HC system is an AC-powered, portable suction device with battery backup that provides localized negative pressure when used with the Cardinal NPWT Dressings to remove fluid, irrigation solutions and infectious materials from the wound. The systems consist of a powered suction pump device with a built-in placement holder for the fluid collection canister, various sizes and shapes of polyurethane foam dressings, canister tubing with clamps and connectors, and polyurethane drapes with adhesive. The systems are intended for use on patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.
The Cardinal Health NPWT PRO HC system provides care in the acute, extended and home care settings.

The Cardinal Health NPWT PRO HC system functions the same as the Cardinal Health NPWT PRO devices. The Cardinal Health NPWT PRO HC system includes a built-in placement holder for the 300cc or 500cc collection canisters. It has a pushbutton ON/OFF operation with five user-selectable pressure settings. The system produces optional negative pressure settings of 50mmHg, 75mmHg, l00mmHg, l25mmHg, and l50mmHg. It has alarms for Low Pressure/Leak, Full Canister, and Low Battery and an alert when the device is due for service. These alarms include both audible and visual indications.

The purpose of this 510(k) submission is to introduce the Cardinal Health NPWT PRO HC system. The Cardinal Health NPWT PRO HC system is identical to the NPWT PRO with the exception of: 1) addition of two motorized pumps for increased air flow volume; (2) one additional battery; and (3) a slightly larger case to accommodate the additional pumps and battery. The user interface for the PRO HC is identical to the PRO.

5. Intended Use(s)

The Cardinal Health NPWT PRO HC system is an integrated wound management system, 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 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.

6. Comparison of Technological Characteristics

This submission describes a new model to the existing cleared Cardinal Health NPWT PRO family: the Cardinal Health NPWT PRO HC. The subject and predicate devices are based on the following same technical elements:

- Continuous and Intermittent negative pressure treatment modes;
- 50mmHg, 75mmHg, 100mmHg, 125mmHg & 150mmHg negative pressure settings;
- Pressure sensing technology within the pump;
- Available for use with 300cc and 500cc canisters;
- Use AC and Rechargeable battery

The NPWT PRO HC differs from the NPTW PRO in that:

- There are two additional motorized pumps for increased air flow volume;
- There is an additional battery; and
- The exterior case is larger to accommodate the additional pumps and battery.

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Tests (Bench)

Testing has been conducted to verify that the modifications to the NPWT PRO HC meet design specifications and demonstrate substantial equivalence to the predicate NPWT PRO device. The list below summarizes the testing conducted for the Cardinal Health NPWT PRO HC device:

- Verification that the PRO HC provides negative pressure at individual pressure settings, identical to the predicate device;
- Verification that the device delivers negative pressure wound therapy in a continuous and intermittent operating mode identical to the predicate device;
- Verification of Canister Full alarm functionality using wound fluid designed to simulate real exudate;
- Verification of system performance and Leak alarm functionality when running with high air leaks at the dressing site;
- Verification of system performance in all pressure settings with simulated exudate; and
- Verification of system performance with all sizes of disposable foam dressing kits and accessories.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Cardinal Health NPWT PRO HC. The system complies with the IEC 60601-1 and IEC 60601-1-11 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator.

Clinical Usability Testing

Testing was conducted using the NPWT PRO device in a home care setting to ensure proper use of the device in the home environment. [Testing conducted with PRO device is directly applicable to the PRO HC device as they have the identical user interface.] The testing included 17 healthcare providers and 16 patients. All participants were provided a user guide and quick reference guide for reference during the study and were asked to perform a series of tasks using the NPWT PRO. All 33 subjects met the predetermined acceptance criteria and no new risks were identified as part of this study.

8. Conclusions

The non-clinical tests, electrical safety and EMC, software verification and validation, and clinical usability testing, demonstrate that the Cardinal Health NPWT PRO HC system is equivalent to the predicate device for the intended use.