DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 19, 2017

Cardinal Health
Tatyana Bogdan-Curvin
Director of Regulatory Affairs
1500 S Waukegan Rd
Waukegan, Illinois 60085

Re: K161418
Trade/Device Name: Cardinal Health NPWT Irrigation Tubing Set, Cardinal Health NPWT Irrigation Delivery Set
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: December 9, 2016
Received: December 12, 2016

Dear Tatyana Bogdan-Curvin:

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" (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 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)*
K161418

Device Name
Cardinal Health NPWT Irrigation Tubing Set and Delivery Set

Indications for Use *(Describe)*

The Cardinal Health NPWT Irrigation Tubing Set and Delivery Set are intended for use with the Cardinal Health NPWT SVED, PRO Family and PRO HC devices, which are 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 fluid including wound exudates, irrigation fluids, body fluids and infectious materials. The NPWT 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 NPWT system is intended for use in acute, extended and home care settings, however wound irrigation is not intended for use in a home care setting.

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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"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."

2. 510(k) SUMMARY

I. Submitter Information

Cardinal Health
1500 S Waukegan Road
Waukegan, IL 60085

Contact Person: Tatyana Bogdan-Curvin
Director, Global Regulatory Affairs
847-887-2325 (office)
tatyana.bogdan-curvin@cardinalhealth.com

Date Prepared: December 7, 2016

II. Device Information

Name of Device:	Cardinal Health Irrigation Tubing Sets
Common Name:	NPWT Tubing Set
Classification Name(s):	Powered Suction Pump (21 CFR 878.4780)
Regulatory Class:	II
Product Code:	OMP

III. Predicate Device

Primary: K150124 Cardinal Health NPWT PRO HC
This predicate has not been subject to a design-related recall.

Reference: K142916 Cardinal Health NPWT SVED
K143016 Cardinal Health NPWT PRO Family

1. Device Description

The Cardinal Health NPWT Irrigation Tubing Set consists of single-lumen PVC tubing, a pinch clamp, an adhesive SpeedConnect flange and a universal luer lock connector wherein the caregiver can attach the universal connector to an irrigation source obtained by the caregiver. The Cardinal Health NPWT Irrigation Delivery Set consists of single-lumen PVC tubing with an integrated irrigation solution bag (to be filled by the caregiver), tubing roller clamp and an adhesive SpeedConnect flange to provide a convenient way for caregivers to utilize the proprietary simultaneous irrigation feature with the various Cardinal Health NPWT devices. The tubing sets are supplied sterile and will be available as new accessories to the PRO HC and PRO family devices.

2. Intended Use(s)

The Cardinal Health NPWT Irrigation Tubing Set and Delivery Set are intended for use with the Cardinal Health NPWT SVED, PRO Family and PRO HC devices, which are 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 fluid including wound exudates, irrigation fluids, body fluids and infectious materials. The NPWT 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 NPWT system is intended for use in acute, extended and home care settings, however wound irrigation is not intended for use in a home care setting.

3. Comparison of Technological Characteristics

The irrigation delivery sets function identically as currently instructed for use with the NPWT SVED device. The tubing sets deliver irrigant to the wound dressing. The difference in the tubing sets is the Irrigation Delivery Set includes an irrigation solution bag whereas the Irrigation Tubing Set does not; there is no difference in operation of the two tubing sets.

4. Performance Data

The following non-clinical performance data were provided in support of the substantial equivalence determination:

- Pressure stability testing with irrigation using a worst-case dressing set spanning the range of pressure settings
- Irrigation bag printed scale accuracy test

5. Conclusions

The non-clinical tests demonstrate that the irrigation tubing sets are compatible with the Cardinal Health NPWT PRO HC and PRO family devices, function as intended and therefore are equivalent to the predicate devices for their intended use.