



October 19, 2018

ConvaTec Limited
Justin Lovelace
Senior Regulatory Affairs Specialist
First Avenue
Deeside, CH5 2NU Gb

Re: K180205

Trade/Device Name: AVELLE Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 14, 2018
Received: September 17, 2018

Dear Justin Lovelace:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Cynthia Chang -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

Indications for Use

510(k) Number (if known)

K180205

Device Name

Avelle™ Negative Pressure Wound Therapy System

Indications for Use (Describe)

The Avelle™ NPWT System is indicated for use on patients that would benefit from a Negative Pressure Wound Therapy (NPWT) device as it may promote wound healing via removal of exudate and infectious materials from low to moderately exuding wound, such as:

- Chronic Wounds e.g. Leg ulcers
- Acute Wounds
- Subacute and dehisced wounds
- Traumatic wounds
- Flaps & Grafts
- Surgically closed incision sites

Avelle™ NPWT System is suitable for use in a hospital, post-acute and home health environment.

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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K180205 - 510(k) Summary

Device: **Avelle Negative Pressure Wound Therapy System**

Applicant: ConvaTec Limited

Contact: Justin Lovelace
Senior Regulatory Affairs Specialist
Telephone: 1-336-542-4745
Email: Justin.Lovelace@convatec.com

Date: October 18, 2018

Trade Name: **Avelle Negative Pressure Wound Therapy System**

Classification Name: Powered Suction Pump (21 CFR 878.4780)

Device Class: Class II

Product Code: OMP

Predicate Device Information

| Predicate Device | 510(k) number | Clearance Date |
|---|----------------------|-----------------------|
| PICO Single Use Negative Pressure Wound Therapy System | K151436 | 01/28/2016 |

Device Description:

The Avelle Negative Pressure Wound Therapy (NPWT) System consists of:

- a disposable battery powered pump
- absorbent wound dressing which is connected to the pump via tubing and luer-lock fittings
- adhesive fixation strips

The Avelle System is intended for single-patient use.

The Avelle pump is disposable, portable and battery-powered. The internal software of the pump limits the use to 30 days. The pump requires 3 AAA lithium batteries to operate. Testing shows that the 3 batteries will power the pump for a minimum of 15.6 days based on testing. A total of 6 AAA lithium batteries (2 sets) are provided with the pump which will power the device

for its entire 30-day lifetime. The disposable battery-powered pump unit is attached to the dressing via the supplied tubing and luer-lock fittings.

The Avelle dressing is comprised of gelling fiber (Hydrofiber®) to absorb wound exudate with negative pressure applied indirectly to the dressing via the Avelle pump. The dressing is applied to the wound and secured around its periphery via its adhesive border and adhesive fixation strips are applied to ensure an adequate seal. The dressing's adhesive surface is protected by a split release liner system comprising of 2 or 3 sections of Low Density Polyethylene (LDPE) release liner (depending on dressing size), which are removed prior to dressing application.

The pump is turned on to apply and maintain a nominal negative pressure of -80mmHg to the dressing. The pump will draw excess wound exudate and infectious materials away from the wound bed and into the Hydrofiber® layers as demonstrated in a simulated use test with a moderately exuding flow of 82 mL over 3 days and a second simulated use test with a low exuding flow of 102 mL over 7 days.

The system will deliver up to 30 days' single patient use for the pump component, and up to 7 days' wear time for the dressing. Each dressing may be used for up to 7 days but may require more frequent changes due to clinical situations. After 30 days of use the pump must be discarded and treatment must be stopped.

The pump unit is provided non-sterile. The Absorbing Dressing (with adhesive fixation strips) is provided sterile via ethylene oxide (EtO) sterilization.

Indications for Use

The Avelle™ NPWT System is indicated for use on patients that would benefit from a Negative Pressure Wound Therapy (NPWT) device as it may promote wound healing via removal of exudate and infectious materials from low to moderately exuding wound, such as:

- Chronic Wounds e.g. Leg ulcers
- Acute Wounds
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- Traumatic wounds
- Flaps & Grafts
- Surgically closed incision sites

Avelle™ NPWT System is suitable for use in a hospital, post-acute and home health environment.

Clinical Data

Clinical Data is not included in this 510(k).

Non-Clinical Performance Data

The AVELLE NPWT is subject to a number of non-clinical performance tests. The AVELLE NPWT meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The list below summarizes the bench testing undertaken and successfully completed for the AVELLE NPWT system:

- Peel testing of the dressing
- Peel testing of the adhesive fixation strips
- Bacterial Barrier testing
- Viral penetration testing
- Distribution of Negative pressure across the dressing
- Absorption assessment of dressing
- Fluid Retention testing
- Moisture Vapor Transmission Rate assessment of dressing
- Pump performance and alarm testing
- Assessing Waterproofness
- Rucking Test of the adhesive strips
- Simulated Use Testing
- Human Factors/Usability Testing

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*, dated May 11, 2005. The software Level of Concern has been evaluated and determined to be **Moderate**, and appropriate documentation included, as recommended by the cited FDA guidance.

Conclusions

In establishing substantial equivalence to the predicate device, ConvaTec evaluated the indications for use, materials, technology, product specifications, and performance of the device and determined the subject device is substantially equivalent to the predicate. The differences do not raise different questions of safety or effectiveness.