June 24, 2026

Convatec Limited, Gdc Building
Michelle Campbell
Senior Regulatory Affairs Specialist
First Ave.
Deeside Industrial Park
Deeside, Flintshire, GB CH5 2NU
United Kingdom

Re: K253263
Trade/Device Name: ConvaVAC™ Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP, FRO
Dated: May 22, 2026
Received: May 22, 2026

Dear Michelle Campbell:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MUSTAFA A. MAZHER -S

For Yu-Chieh Chiu PhD,
Assistant Director
DHT4B: Division of Plastic and Reconstructive 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253263

Device Name
ConvaVAC™ Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
The ConvaVAC™ Negative Pressure Wound Therapy (NPWT) System is intended for patients who would benefit from negative pressure wound therapy for wound management via the removal of fluids including exudate, infectious materials and wound debris.

The ConvaVAC™ NPWT System is indicated for low to moderately exuding wounds such as:

- Chronic wounds i.e., diabetic foot ulcers, leg ulcers such as venous, arterial, and pressure ulcers
- Traumatic wounds
- Dehisced wounds
- Flaps and grafts
- Closed surgical incisions

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.

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

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510(k) Summary

K253263

Device:	ConvaVAC™ Negative Pressure Wound Therapy System
Date:	June 24, 2026
Applicant:	Convatec Limited
Primary Contact:	Michelle Campbell Senior Regulatory Affairs Specialist michelle.campbell@convatec.com +44 7990 444 051
Secondary Contact	Ken Fergusson Senior Regulatory Affairs Manager ken.fergusson@convatec.com +44(0) 7714 387 682
Trade Name:	ConvaVAC™ Negative Pressure Wound Therapy System
Classification Name:	Powered Suction Pump (21 CFR 878.4780)
Device Class:	Class II
Product Codes:	OMP FRO

Predicate Device

Predicate Device	**510(k) Number**	**Clearance Date**
AVELLE™ Negative Pressure Wound Therapy System	K180205	10/19/2018
Reference Device	**510(k) Number**	**Clearance Date**
AQUACEL™ Ag+ EXTRA Enhanced Hydrofiber™ Dressing with Silver and Strengthening Fiber	K173675	07/20/2018

Device Description

The ConvaVAC™ single use Negative Pressure Wound Therapy System (sNPWT) consists of:

- a disposable, battery powered pump which is connected to the dressing via tubing with proprietary fittings (ConvaVAC™ sNPWT Pump).
- an absorbent wound dressing (ConvaVAC™ sNPWT Dressing).
- an absorbent, antimicrobial wound dressing (ConvaVAC™ Ag+ sNPWT Dressing).
- adhesive fixation strips.

The ConvaVAC ™ sNPWT System is intended for single patient use.

The ConvaVAC™ sNPWT Pump is disposable, portable and battery powered, supplied in three variants of therapy duration, 7-, 15- or 30-days. It is designed to deliver up to 7-, 15- or 30-days of therapy in the hospital or home environment. The pump generates and maintains a nominal 80 mmHg negative pressure. The pump is provided with either 2 or 4 AA batteries (2 for the 7- and 15-day pumps and 4 for the 30 day pumps) which testing has shown is sufficient for the expected therapy conditions. The pump is attached to the dressing via the supplied tubing and luer-lock fittings.

The ConvaVAC™ sNPWT dressing is supplied in two variants; the ConvaVAC™ sNPWT dressing and the ConvaVAC™ Ag+ sNPWT dressing, which are identical in structure except that the Ag+ variant contains More Than Silver™ technology. Negative pressure is applied to the dressing via activation of the pump. The dressing is applied to the wound and secured via its adhesive border around the periphery of the dressing. Adhesive fixation strips are applied to ensure an adequate seal. The dressing's adhesive surface and wound contact layer is protected by a Low-Density Polyethylene (LDPE) split release liner system in 2 or 3 sections (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. This draws excess wound exudate and infectious materials away from the wound bed and into the dressing, as demonstrated in vitro testing.

The system will deliver negative pressure wound therapy for up to 7-, 15- or 30 days' (dependent on the variant of the pump) single patient use for the pump component. Once the maximum duration for the pump variant has been reached it will switch off and be discarded.

The dressing should be reapplied according to the Instructions for Use.

The pump is provided non-sterile. The absorbent dressing and adhesive fixation strips are provided sterile via ethylene oxide (EtO) sterilization.

Indications for Use

The ConvaVAC™ NPWT System is intended for patients who would benefit from negative pressure wound therapy for wound management via the removal of fluids including exudate, infectious materials and wound debris.

The ConvaVAC™ NPWT System is indicated for low to moderately exuding wounds such as:

- Chronic wounds i.e., diabetic foot ulcers, leg ulcers such as venous, arterial, and pressure ulcers
- Traumatic wounds
- Dehisced wounds
- Flaps and grafts
- Closed surgical incisions

Technological Characteristics

The ConvaVAC™ sNPWT System has similar technological characteristics compared to the predicate and reference devices. The system has similar components to the predicate device with the exception of the following:

- The ConvaVAC™ sNPWT System offers a choice of pumps with different therapy durations of 7-, 15- or 30 days. The pumps provide the same level of nominal negative pressure regardless of the variant, as with the predicate device, the integrated software controlling the pump will switch the pump off at the end of its pre-determined use duration. The therapy duration options are intended to provide the healthcare professional with a choice of pump most suitable to their patient's needs.
- The option of ConvaVAC™ Ag+ sNPWT antimicrobial dressing as part of the system. The antimicrobial dressing is for use on the same types of wounds and has the same functionality under negative pressure wound therapy as demonstrated in vitro.
- The inclusion of multisite dressings and a 16cm x 31cm dressing into the dressing ranges of the ConvaVAC™ sNPWT dressings and the ConvaVAC™ Ag+ sNPWT dressings. The inclusion of the 16cm x 31cm and the multi-site dressings into the ConvaVAC™ range has no impact on the safety and effectiveness of the ConvaVAC™ sNPWT system. The additional dressing sizes fall withing the range of dressings.
- The tube set is manufactured from polyurethane and has bespoke luer connectors. The materials are biocompatible, and performance is the same. The bespoke connectors ensure that the pump is only able to be connected to ConvaVAC™ sNPWT dressings.
- The ConvaVAC™ sNPWT dressings include a superabsorbent layer. Superabsorbent layers are commonly used in Advanced Wound Care Dressings to improve fluid management within the dressing. The superabsorber does not affect the delivery of the negative pressure to the wound as demonstrated in vitro.

The differences between the ConvaVAC™ sNPWT System and the predicate and reference devices do not raise any new questions regarding the safety and effectiveness of the system. Based on the information provided in this 510(k) submission, the ConvaVAC™ sNPWT System is considered substantially equivalent to the currently marketed Avelle™ NPWT system technology aspects of the device in terms of fundamental scientific technology.

Clinical Data

Clinical data is not included in this 510(k) submission.

Summary of Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the ConvaVAC™ sNPWT System, and in showing substantial equivalence to the predicate device, Convatec completed non-clinical performance tests. The ConvaVAC™ sNPWT System meets all the requirements for the overall design, sterilization, biocompatibility and electrical safety, confirming that the design output meets the design inputs and specification for the device.

The ConvaVAC dressing is categorized as a surface device on breached or compromised surfaces for limited contact duration (<= 24 hours).

The list below summarizes the bench testing undertaken and successfully completed for the ConvaVAC™ sNPWT System: Peel testing of the dressing –All samples met the acceptance criteria.

- Peel testing of the adhesive fixation strips (average force) - all samples met the acceptance criteria
- Distribution of Negative pressure across the dressing – the largest surface area and the longest dressing tested; acceptance criteria were met for distribution of negative pressure across the dressing.
- Absorption assessment of dressing – Pass
- Retention testing – All samples met the acceptance criteria.
- Moist Vapor Transmission Rate (MVTR) assessment of dressing- Once fluid reaches the dressing outer film layer the ConvaVAC™ sNPWT dressing's MVTR is sufficient to handle fluid effectively as recorded for the low exudate flow rate test data
- Pump performance testing – All samples met the acceptance criteria.
- Simulated Use Testing – All samples met the acceptance criteria.
- Based on in-vitro studies, the Silver in the ConvaVAC™ Ag+ is shown to reduce microbial colonization of the dressing. The claim of reduction in microbial colonization of the dressing has not been established with human clinical data, nor has a clinical impact associated with this claim or with the presence of silver in the device been demonstrated

The software documentation in this submission has been assembled in accordance with the recommendations in FDA Guidance document *Content of Premarket Submissions for Device Software Functions*, dated June 14, 2023. The Documentation Level has been evaluated and determined to be Basic; appropriate documentation has been included as per FDA Guidance.

Conclusion

The ConvaVAC™ sNPWT system is substantially equivalent to the currently marketed predicate device Avelle™ NPWT system in terms of indications for use, technological characteristics and safety and effectiveness. Substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) pre-market notification. These tests demonstrate that the ConvaVAC™ sNPWT System design inputs, user needs and the requirements specified in the FDA-recognized consensus standards and guidance documents. The ConvaVAC™ sNPWT System is as safe and effective as the predicate device and does not raise any new safety and/or effectiveness concerns.