November 21, 2025

DeRoyal Industries, Inc.
Mary Catherine Reeves
Senior Regulatory Affairs Manager
200 DeBusk Lane
Powell, Tennessee 37849

Re: K250586
Trade/Device Name: Prospera Spectruum Negative Pressure Wound Therapy Black Foam Kits and White Foam Accessory
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: February 27, 2025
Received: February 27, 2025

Dear Mary Catherine Reeves:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250586

Device Name
Prospera Spectruum Negative Pressure Wound Therapy Black Foam Kits and White Foam Accessory

Indications for Use *(Describe)*
The Prospera Spectruum™ Negative Pressure Wound Therapy System is a wound management system intended for use in acute, extended and home care settings.

When used on open wounds, it is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. When used on closed surgical incisions, it is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

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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510(k) #: K250586

510(k) Summary

Prepared on: 2025-10-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	DeRoyal Industries, Inc.
Applicant Address	200 DeBusk Lane Powell TN 37849 United States
Applicant Contact Telephone	865-362-6112
Applicant Contact	Ms. Mary Catherine Reeves
Applicant Contact Email	mreeves@deroyal.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Prospera Spectruum Negative Pressure Wound Therapy Black Foam Kits and White Foam Accessory
Common Name	Powered suction pump
Classification Name	Negative Pressure Wound Therapy Powered Suction Pump
Regulation Number	878.4780
Product Code(s)	OMP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K133276	V.A.C. Therapy Wound Dressings	OMP
K213853	RENASYS™-WF White Foam NPWT Dressing	OMP

Device Description Summary

21 CFR 807.92(a)(4)

The Prospera Spectruum™ Negative Pressure Wound Therapy (NPWT) System is a medical device designed to allow for wound management through controlled negative pressure. The NPWT device and canister work in tandem to generate and maintain the specified negative pressure level, while the dressing kit provides fluid management and coverage over the wound site. This system provides flexibility and targeted therapy to manage the wound-healing environment in acute, subacute, chronic, and surgically closed wounds, suitable for use in diverse care settings, including hospital, extended, and home care.

The Prospera Spectruum Negative Pressure Wound Therapy System consists of:
• Prospera Spectruum Negative Pressure Wound Therapy Unit
• A disposable canister which collects wound exudate
• Prospera Spectruum Negative Pressure Wound Therapy Kit which includes a wound interface dressing, semi-occlusive wound drape, and dual lumen dressing connection.
• Optional White Foam Accessory

The dressing kit is available in multiple sizes, allowing for the use of either black foam alone or with an optional White Foam Accessory, based on wound characteristics and clinical needs. The black foam, as part of the primary dressing, is a hydrophobic polyurethane foam designed to assist in uniform pressure distribution across the wound bed. The optional white foam, made of polyvinyl alcohol (PVA) is a highly retentive material that supports fluid absorption and even pressure distribution. Both foams are secured with semi-occlusive wound drape and connected to the NPWT device via tubing, enabling removal of wound exudate and infectious materials.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Prospera Spectruum™ Negative Pressure Wound Therapy System is a wound management system intended for use in acute, extended and home care settings.

When used on open wounds, it is intended to create an environment that allow wound management by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. When used on closed surgical incisions, it is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the predicate and subject devices are the same.

Technological Comparison 21 CFR 807.92(a)(6)

Prospera Spectruum Negative Pressure Wound Therapy Black Foam Kits include Black foam dressing as a wound interface that is intended to be placed into the wound bed. The Black foam dressing has open reticulated pores to distribute negative pressure across the wound bed and to facilitate the removal of exudate and infectious material. The optional white foam, made of polyvinyl alcohol (PVA) is a highly retentive material that supports fluid absorption and pressure distribution. Both foams are secured with semi-occlusive wound drape and connected to the NPWT device via tubing, enabling removal of wound exudate and infectious materials. The Transeal® MAXX semi-occlusive wound drape is placed over the foam to provide a sealed environment for the application of negative pressure and to maintain a moist wound environment. The Prospera Spectruum Contour Dome with dual lumen connects the dressing to the canister attached to the Prospera Spectruum negative pressure wound therapy unit and facilitates the application of pressure and removal of wound exudate.

The subject and predicate devices are based on the following same technological characteristics:
- Intended use
- Indicated wound types
- Use environment (acute, extended and home care settings)
- Intended for use as compatible kits within a Negative Pressure Wound Therapy System
- Kit components

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following testing has been conducted to support the conclusion that the proposed device is substantially equivalent to the predicate device:
- Bench testing demonstrates the Prospera Spectruum Black Foam Kits and White Foam Accessory when used as part of the Prospera Spectruum NPWT System maintains negative pressure within specifications and manages fluid exudate without unexpected alarms.
- Package Integrity testing to ensure the sterile barrier integrity is maintained throughout its labeled shelf life.
- Product performance testing of dressing components after sterilization to verify the product functions as intended throughout its shelf life.

The tests, procedures, and acceptance standards utilized to prove substantial equivalency with the predicate devices are described in detail in the design verification protocol and summary report documents. In all instances, the Prospera Spectruum Black Foam Kits and White Foam Accessory functioned as intended and all test results observed were as expected.

The subject device's fundamental technology and principles of operation are the same compared to the predicate devices. The subject device's Intended Use and Indications for use are the same as the predicate devices as cleared under K133276 and K213853.The performance data demonstrates that the Prospera Spectruum Black Foam Kits and White Foam Accessory is as safe and effective as the predicate devices. Thus, the Prospera Spectruum Black Foam Kits and White Foam Accessory is substantially equivalent to the predicate devices.