April 18, 2024

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

Re: K230233
Trade/Device Name: Prospera Spectruum Negative Pressure Wound Therapy Unit (NP-7000)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 27, 2023
Received: January 27, 2023

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.

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.
Assistant Director
DHT4B: Division of Infection Control
and 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)*
K230233

Device Name
Prospera Spectruum™ Negative Pressure Wound Therapy System

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.

The Prospera Spectruum™ Negative Pressure Wound Therapy System is only intended to be used with the Granufoam wound interface dressing and V.A.C. Drape components from the V.A.C. Therapy Wound Dressing kit.

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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510(k) #: K230233

510(k) Summary

Prepared on: 2024-04-18

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 System
Common Name	Powered suction pump
Classification Name	Negative Pressure Wound Therapy Powered Suction Pump
Regulation Number	878.4780
Product Code	OMP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183543	ACTIV.A.C. Therapy Unit	OMP
K201571	ACTIV.A.C.™ Negative Pressure Wound Therapy System	OMP
K133276	V.A.C. Therapy Wound Dressings	OMP

Device Description Summary

21 CFR 807.92(a)(4)

The Prospera Spectruum™ Negative Pressure Wound Therapy Unit (NP-7000) is a component of the Prospera Spectruum Negative Pressure Wound Therapy (NPWT) System.

The Prospera Spectruum™ Negative Pressure Wound Therapy System consists of:
- Prospera Spectruum™ Negative Pressure Wound Therapy Unit
- Disposable canister which collects wound exudate
- Prospera Spectruum™ Contour Dome

The Prospera Spectruum™ Negative Pressure Wound Therapy System is only intended to be used with the Granufoam wound interface dressing and V.A.C.Drape components from the V.A.C. Therapy Wound Dressing kit.

The Prospera Spectruum™ Negative Pressure Wound Therapy Unit (NP-7000) is a portable, rechargeable battery and mains powered, reusable, software-controlled unit used with a canister that can provide continuous or variable applications of negative pressure to a wound in the user defined range between 25mmHg and 200mmHg. The Prospera Spectruum™ Negative Pressure Wound Therapy System is designed for use in home, acute or extended care settings.

The compatible dressing components include a wound interface dressing applied to the wound covered with a semi-occlusive drape and is connected to the canister of the Prospera Spectruum™ Negative Pressure Wound Therapy Unit (NP-7000) via a dual lumen

dressing connection. This connection allows for the distribution of negative pressure to the wound bed and removal of wound exudate which is transported to the collection canister via the lumen.

The software within the Prospera Spectruum™ Negative Pressure Wound Therapy Unit (NP-7000) provides and maintains the prescribed pressure within the user defined range as well as alarming as needed when performance is reduced below the defined threshold. The alarms alert the user to conditions such as tubing blockages, a full canister, inactive therapy, low battery, and leaks in the system.

Additional features include:
- GPS for optional inventory management support
- Therapy history report via USB data port
- Pre-set therapy options
- Event Log
- User interface with flat buttons requiring depression for activation to reduce unintentional screen changes
- Confirmation screen to provide a visual notification to the user prior to device shutdown. The Prospera Spectruum™ Negative Pressure Wound Therapy Unit (NP-7000) will continue delivering therapy and will not power off until the user stops therapy and acknowledges via user interface that the intent is to power off the unit.

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 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.

The Prospera Spectruum™ Negative Pressure Wound Therapy System is only intended to be used with the Granufoam wound interface dressing and V.A.C. Drape components from the V.A.C. Therapy Wound Dressing kit.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use of the predicates and subject device are similar. The indicated wound types and care settings are identical.

The inclusion of the wound dressing compatibility statement in the subject device's Intended Use statement indicating the use of the subject device with the legally marketed wound dressing components is supported by the tertiary predicate, K133276, which is the legally marketed NPWT Dressing Kit that is compatible with the primary and secondary predicates, K183543 and K201571, ACTIV.A.C.™ Negative Pressure Wound Therapy System NPWT System. The tertiary predicate includes a dressing connection (equivalent to the Prospera Spectruum™ Contour Dome), wound interface dressing (Granufoam) and secondary semi-occlusive wound drape (V.A.C.Drape). These components work together to dress the wound and connect it to the predicate NPWT system. The Prospera Spectruum™ system as described in this submission will work using the Prospera Spectruum™ Contour Dome to connect the wound dressed by the legally marketed wound dressing components cleared under K133276, Granufoam and V.A.C.Drape, to the Prospera Spectruum™ NPWT Unit (NP-7000) and canister to apply negative pressure and remove exudate. Functional bench testing has been completed using these legally marketed wound dressing components with the Prospera Spectruum™ NPWT Unit (NP-7000), Canister, and Contour Dome to establish safe and effective performance when used together as a system and support substantial equivalence to the predicates.

These differences in the Indication for Use statements between the subject and predicate devices have no impact on the intended therapeutic use of the device and do not constitute a new intended use of the device when used as labeled.

Technological Comparison

21 CFR 807.92(a)(6)

Controlled delivery of negative pressure to the wound site is the technological principle for both the subject and predicate devices. The software-controlled powered therapy unit applies negative pressure to the wound bed via the dual lumen tubing connected to compatible wound dressing components and exudate is removed from the wound is collected the attached canister.

The subject and predicate device are based on the following same technological elements:
- Intended use
- Indicated wound types
- Negative pressure therapy specifications
- Use environment (acute, extended and home care settings)
- System components: powered NPWT unit, disposable canisters, dressing connection with lumen and compatible wound dressing

components including a wound interface dressing and semi-occlusive drape.

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:

- Conformance to the most current General Requirements for Basic Safety and Essential Performance 60601-1 standards.
- Software has been assessed in accordance with FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005).
- Prospera Spectruum™ bench testing demonstrates the unit maintains negative pressure within specifications and manages fluid exudate without unexpected alarms.
- Usability Testing was performed per ISO 62366-1 and ANSI/AAMI HE 75. Testing was performed using lay users who represent patients and lay caregivers to support the use of the device in the home environment and with clinicians to support the use of the device in the hospital.

In all instances, Prospera Spectruum™ NPWT System functioned as intended and all test results observed were as expected.

Clinical Tests Not Applicable

The Prospera Spectruum™ NPWT system is as safe and effective as the predicates ACTIV.A.C.™ Therapy System (K183543 and K201571) and V.A.C. Therapy Wound Dressings (K133276). The subject device's fundamental technology and principles of operation for the Prospera Spectruum™ NPWT System are the same compared to the predicate devices. The subject device's Indications for Use are the same as the predicate devices. The identified technological differences between the Prospera Spectruum™ NPWT System and its predicate devices could not significantly affect the safety or effectiveness of the device, nor did they represent a major change in intended use or safety. The performance data demonstrates that the Prospera Spectruum™ NPWT System is as safe and effective as the predicates. Thus, the Prospera Spectruum™ NPWT System is substantially equivalent to the predicates.