



October 3, 2025

Alleva Medical Devices
% Mona Advani
Regulatory Consultant
Addwin Consulting
13260 Middleton Farm Ln
Herndon, Virginia 20171

Re: K251646

Trade/Device Name: extriCARE® 1000 Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 28, 2025
Received: May 29, 2025

Dear Mona Advani:

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.

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

Indications for Use

510(k) Number (if known)

K251646

Device Name

extriCARE® 1000 NPWT System

Indications for Use (Describe)

The extriCARE® 1000 NPWT System is intended to generate negative pressure to remove wound exudates, infectious material, and tissue debris from the wound bed.

The extriCARE® 1000 NPWT System is intended for use in wounds with low to moderate levels of exudate. Appropriate wound types include:

- Chronic wounds
- Acute wounds
- Traumatic wounds
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcer wounds (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

The extriCARE® 1000 NPWT System is intended for use in healthcare facilities. The extriCARE® 1000 NPWT System is intended for use with extriCARE® 1000 Bandage Dressings.

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) Summary
[21 CFR 807.92(c)]

DATE PREPARED:	October 3 rd 2025
APPLICANT	Alleva Medical Devices 1050 W. Central Avenue, Ste B Brea, CA 92821
CONTACT	Mona Advani Regulatory Consultant Addwin Consulting Corporation
TRADE NAME:	extriCARE® 1000 NPWT System
DEVICE CLASSIFICATION:	Class II per 21 CFR 878.4780
CLASSIFICATION NAME:	Negative Pressure Wound Therapy Pump
PRODUCT CODE	OMP
PREDICATE DEVICE:	extriCARE® 1000 Negative Pressure Wound Therapy System (K213906)

Indications for Use

The extriCARE® 1000 NPWT System is intended to generate negative pressure to remove wound exudates, infectious material, and tissue debris from the wound bed.

The extriCARE® 1000 NPWT System is intended for use in wounds with low to moderate levels of exudate. Appropriate wound types include:

- Chronic wounds
- Acute wounds
- Traumatic wounds
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcer wounds (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

The extriCARE® 1000 NPWT System is intended for use in healthcare facilities. The extriCARE® 1000 NPWT System is intended for use with extriCARE® 1000 Bandage Dressings.

Device Description

The extriCARE® 1000 Negative Pressure Wound Therapy (NPWT) System consists of a portable pump unit intended to generate vacuum pressure to remove low to moderate level of wound exudates, infectious material, and tissue debris from the wound bed. Three preset vacuum pressures can be selected by the user – 80, 100, and 125mmHg. The extriCARE® 1000 NPWT System is packaged and provided with the following components:

1. extriCARE® 1000 Negative Pressure Wound Therapy Pump
2. extriCARE® 1000 50cc Collection Canister
3. Adapter Power Cord(5VDC)
4. extriCARE® 1000 Bandage Dressing/K140634 (this component is provided separately)

Summary of Technological Characteristics

The extriCARE® 1000 pump shares the same operating principles with its predicate device, by having an air pump, a solenoid valve, and a pressure sensor working in conjunction to deliver a specific target vacuum pressure on the wound bed. When the therapy begins, air and wound exudate are removed from the underside of the dressing (wound bed) via the connection tubing into the collection canister until the target vacuum is reached. A pressure sensor inside the pump, along with a proprietary algorithm, approximates and monitors the pressure on the wound site. If a leakage on the wound dressing occurs, the device activates its air pump to remove air until the target vacuum is re-established. In the event that the actual vacuum pressure exceeds target vacuum pressure, a solenoid valve and a check valve will act to allow ambient air into the system to lower the vacuum pressure to the desired level. Modifications from the predicate device include a charger port to allow the device to be powered directly by a 5VDC and a software automatic system locking feature to minimize the risk of accidental settings changes.

Comparison of Subject Device to the Predicate Device

Selected Features	extriCARE® 1000 NPWT System Subject Device	extriCARE® 1000 NPWT System Predicate Device K213906	Equivalence Rationale
Indications for Use	<p>The extriCARE® 1000 NPWT System is intended to generate negative pressure to remove wound exudates, infectious material, and tissue debris from the wound bed.</p> <p>The extriCARE® 1000 NPWT System is intended for use in wounds with low to moderate levels of exudate. Appropriate wound types include:</p> <ul style="list-style-type: none"> • Chronic wounds • Acute wounds • Traumatic wounds • Subacute and dehisced wounds • Partial-thickness burns • Ulcer wounds (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions <p>The extriCARE® 1000 NPWT System is intended for use in healthcare facilities. The extriCARE 1000 NPWT System is intended for use with extriCARE® 1000 Bandage Dressings.</p>	<p>The extriCARE® 1000 NPWT System is intended to generate negative pressure to remove wound exudates, infectious material, and tissue debris from the wound bed.</p> <p>The extriCARE® 1000 NPWT System is intended for use in wounds with low to moderate levels of exudate. Appropriate wound types include:</p> <ul style="list-style-type: none"> • Chronic wounds • Acute wounds • Traumatic wounds • Subacute and dehisced wounds • Partial-thickness burns • Ulcer wounds (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions <p>The extriCARE® 1000 NPWT System is intended for use in healthcare facilities.</p>	Similar
Contraindications	•Exposed vessels, organs, or nerves.	Exposed vessels, organs, or nerves.	Identical

Selected Features	extriCARE® 1000 NPWT System Subject Device	extriCARE® 1000 NPWT System Predicate Device K213906	Equivalence Rationale
	<ul style="list-style-type: none"> •Anastomotic sites. •Exposed arteries or veins in a wound. •Fistulas, unexplored or non-enteric. •Untreated osteomyelitis. •Malignancy in the wound. •Excess amount of necrotic tissue with eschar. •Wounds which are too large or too deep to be accommodated by the dressing. •Inability to be followed by a medical professional or to keep scheduled appointments. •Allergy to urethane dressings and adhesives. •Use of topical products which must be applied more frequently than the dressing change schedule allows. 	<ul style="list-style-type: none"> •Anastomotic sites. •Exposed arteries or veins in a wound. •Fistulas, unexplored or non-enteric. •Untreated osteomyelitis. •Malignancy in the wound. •Excess amount of necrotic tissue with eschar. •Wounds which are too large or too deep to be accommodated by the dressing. •Inability to be followed by a medical professional or to keep scheduled appointments. •Allergy to urethane dressings and adhesives. •Use of topical products which must be applied more frequently than the dressing change schedule allows. 	
Prescription Use	Yes	Yes	Identical
Use Settings	Healthcare Facilities	Healthcare Facilities	Identical
Use	Multi-Patient	Multi-Patient	Identical
Compatibility With	Compatible with extriCARE Bandage Dressing cleared under K110078	Compatible with extriCARE Bandage Dressing cleared under K110078	Identical
General Operating Principle	A vacuum pump generates vacuum and delivers to the	A vacuum pump generates vacuum and delivers to the	Identical

Selected Features	extriCARE® 1000 NPWT System Subject Device	extriCARE® 1000 NPWT System Predicate Device K213906	Equivalence Rationale
	wound bed via an airtight, disposable, sterile wound dressing	wound bed via an airtight, disposable, sterile wound dressing	
System Components	Pump Unit, 50cc Collection Canister, Adapter Power Cord, Two AA Batteries, Used in Conjunction with Bandage Dressing cleared in K110078.	Pump Unit, 50cc Collection Canister, Two AA Batteries, Used in Conjunction with Bandage Dressing cleared in K110078.	Risk Assessment determined no safety concerns based on new EMC, Bench, and Software Validation for addition of the Adapter Power Cord
Vacuum Source	DC-Powered Diaphragm Pump	DC-Powered Diaphragm Pump	Identical
Pressure Monitoring Mechanism	Pressure Sensor Connected to the Inlet	Pressure Sensor Connected to the Inlet	Identical
Pressure Regulation	Microprocessor and Solenoid Valve	Microprocessor and Solenoid Valve	Identical
Pump Dimensions WxHxD (in)	3.2x4.8x1.3	3.2x4.8x1.3	Identical
Canister	Yes, 50cc	Yes, 50cc	Identical
Pressure Range mmHg	80, 100, 125	80, 100, 125	Identical

Summary of Non-Clinical Testing

Non-clinical and appropriate IEC testing has been completed to demonstrate that the extriCARE® 1000 NPWT pump is performing as intended, has performance characteristic that are substantially equivalent to the listed predicate device, and conforms to internal standards and regulations.

Software verification and validation activities were completed to support the modifications to the system. Based on the device's intended use, the design of the device, and the risks of the device software function(s) in the context of the device's intended use, Alleva Medical Devices determined that Enhanced software documentation was required and completed. During the validation activities all activities met requirements, and no unresolved anomalies were found.

Clinical Testing (807.92(b)(2))

No clinical testing is required to support this 510(k) submission. No clinical testing has been performed.

Summary of Substantial Equivalence

All characteristics of the extriCARE® 1000 are identical with the exception of the two features as presented in the table below.

Selected Features	extriCARE® 1000 NPWT System Subject Device	extriCARE® 1000 NPWT System Predicate Device, K213906
Locking Feature	System Automatically Locks	No Self-Locking Feature
Power Source	Direct 5VDC/2A power supply/ 2x AA 1.5V alkaline batteries	2x AA 1.5V alkaline batteries

Based on its operating principles, specifications, and indications for use, the extriCARE® 1000 is substantially equivalent to its predicate device. The system does not raise any new risks when compared to the predicate device.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Alleva Medical Devices, has demonstrated that the extriCARE® 1000 NPWT System is substantially equivalent to the predicate device.