February 9, 2023

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

Re: K221223
Trade/Device Name: extriCARE® 3000 Negative Wound Pressure Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 10, 2023
Received: January 12, 2023

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 (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/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 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 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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of General 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)*
K221223

Device Name

extriCARE®3000 Negative Pressure Wound Therapy System

Indications for Use *(Describe)*

The extriCARE® 3000 Negative Pressure Wound Therapy System is intended to generate negative pressure or suction to remove wound exudates, infectious material, and tissue debris from the wound bed. It is indicated for the following wound types:

- chronic
- acute
- traumatic
- subacute and dehisced wounds
- partial-thickness burns
- ulcers (such as diabetic or pressure)
- flaps and grafts.

The extriCARE® 3000 Negative Pressure Wound Therapy System is intended for use in healthcare facilities.

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

[as required by 21 CFR 807.92(c)]

Alleva Medical Devices

extriCARE®3000 Negative Pressure Wound Therapy System K221223

DATE PREPARED:	February 9, 2023
APPLICANT	Alleva Medical Devices 1050 West Central Avenue, Unit B Brea, CA 92821
CONTACT	Mona Advani Regulatory Consultant Addwin Consulting Corporation Phone: 650-575-5819 Email: mona@addwinconsulting.com
TRADE NAME:	extriCARE® 3000 Negative Pressure Wound Therapy System
DEVICE CLASSIFICATION:	Class II per 21 CFR 878.4780
CLASSIFICATION NAME:	Powered Suction Pump
PRODUCT CODE	OMP
PREDICATE DEVICE:	extriCARE 3600 Negative Pressure Wound Therapy System (K132225)

INDICATION FOR USE:

The extriCARE® 3000 Negative Pressure Wound Therapy System is intended to generate negative pressure or suction to remove wound exudates, infectious material, and tissue debris from the wound bed. It is indicated for the following wound types:

- chronic
- acute
- traumatic
- subacute and dehisced wounds
- partial-thickness burns
- ulcers (such as diabetic or pressure)
- flaps and grafts.

The extriCARE® 3000 Negative Pressure Wound Therapy System is intended for use in healthcare facilities.

DEVICE DESCRIPTION:

The extriCARE 3000 Negative Pressure Wound Therapy (NPWT) pump is a portable, rechargeable, battery-powered pump intended to generate negative pressure or suction to remove wound exudates, infectious material, and tissue debris from the wound bed. The extriCARE 3000 Negative Pressure Wound Therapy (NPWT) is packaged and provided with the following components:

1. extriCARE 3000 Negative Pressure Wound Therapy Pump
2. extriCARE 3000 100cc Collection Canister

The extriCARE® 3000 Negative Pressure Wound Therapy (NPWT) pump accessories that are included in this 510(k) application and will be commercialized separately are the following:

1. extriCARE® 3000 100cc Collection Canister (additional canister replacements)
2. extriCARE® 3000 400cc Collection Canister

COMPARISON WITH PREDICATE DEVICE:

The extriCARE® 3000 Negative Pressure Wound Therapy System shares the same technological principle with its predicate device, in which a vacuum is generated by a vacuum pump and delivered to the wound bed via airtight wound dressing to remove wound exudate and provide vacuum pressure on the wound bed. The vacuum pressure is applied for a specified period of time and intensity, according to the physician's prescription. The wound dressings used in this system are identical to those previously cleared under the predicate submissions.

Similar to the predicates, vacuum is generated via a battery-powered miniature air pump. When the therapy begins, air and wound exudate are removed from the dressing underside (wound site) via the connection tubing to the collection canister until the target vacuum is reached. A pressure sensor inside the pump, along with a proprietary algorithm, monitors and controls the pressure on the wound site. Various user settings can be adjusted through the device touchscreen on the front. Other sensors are present to provide alarms if certain compromising issues, such as blockage or leakage, are encountered. See the table below for review of the comparison with the predicate device.

Comparison Summary of the extriCARE 3000 NPWT System to the Predicate Device

Item	Subject Device	Predicate Device
Name	*extriCARE ®3000 Negative Wound Therapy System*	*extriCARE 3600 Negative Pressure Wound Therapy System*
Manufacturer	Alleva Medical Devices, LLC	Devon Medical Products
510(k) Number	K221223	K132225
FDA Product Code	OMP	OMP
Regulation Number	878.4780	878.4780
Indication for Use	The extriCARE® 3000 NPWT System is intended to generate negative pressure or suction to remove wound exudates, infectious material, and tissue debris from the wound bed. It is indicated for the following wound types: • chronic • acute • traumatic • subacute and dehisced wounds • partial-thickness burns • ulcers (such as diabetic or pressure) • flaps and grafts. The extriCARE® 3000 Negative Pressure Wound Therapy System is intended for use in healthcare facilities.	The extriCARE 3600 Negative Pressure Wound Therapy System is indicated for wound management via the application negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The system is indicated for the following wound types: ▪ chronic, ▪ acute, ▪ traumatic, ▪ subacute and dehisced wounds, ▪ partial-thickness burns ulcers (such as diabetic or pressure), and flaps and grafts
Contraindications	▪ Exposed vessels, organs, or nerves. ▪ Anastomotic sites. ▪ Exposed arteries or veins in a wound. ▪ Fistulas, unexplored or non-enteric. ▪ Untreated osteomyelitis. ▪ Malignancy in the wound. ▪ Excess amount of necrotic	▪ Exposed vessels, organs, or nerves. ▪ Anastomotic sites. ▪ Exposed arteries or veins in a wound. ▪ Fistulas, unexplored or non-enteric. ▪ Untreated osteomyelitis. ▪ Malignancy in the wound. ▪ Excess amount of necrotic

Item		Subject Device	Predicate Device
		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	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
Principle of Operation		A vacuum pump generates vacuum. A collection canister is connected to the vacuum pump, and a tubing connecting the wound dressing and the canister brings wound exudate	A vacuum pump generates vacuum. A collection canister is connected to the vacuum pump, and a tubing connecting the wound dressing and the canister brings wound exudate
Design	**Vacuum mode**	Continuous and intermittent	Continuous and intermittent
	Intermittent mode	5 minutes at target vacuum, then 2 minutes at 20mmHg	5 minutes at target vacuum, then 2 minutes at 20mmHg
	Collection canister sizes	100cc and 400cc	400cc and 1000cc
Other Features	**Prescription Use**	Yes	Yes
	Use Settings	Healthcare Facilities	Healthcare Facilities
	Compatibility with extriCARE dressings	Compatible for use with extriCARE Foam Kit and Bandage Dressings, cleared under K140634 and K110078, respectively	Compatible for use with extriCARE Foam Kit and Bandage Dressings, cleared under K140634 and K110078, respectively

NON-CLINICAL TESTING / PERFORMANCE DATA:

Non-clinical testing has been completed to demonstrate that the extriCARE 3000 NPWT System performs as intended and has performance characteristic that are substantially equivalent to or superior to the listed predicate device. The following is a summary of the testing that was performed or addressed in this submission.

Sterility

The extriCARE 3000 and its predicate device are provided non-sterile.

Biocompatibility

The extriCARE 3000 pump unit and collection canisters only have transient contact with the *user*. No additional biocompatibility testing was conducted on the pump and collection canisters.

Electrical Testing

Electrical Testing was performed using the test standards IEC 60601-1:2005+AMD1:2012: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* and IEC 60601-1-11:2015: *Medical electrical equipment – Part 11: General requirements for basic safety and essential performance – Collateral Standard*. Testing concluded that the Device met all test requirements for electrical safety.

EMC Evaluation

Electromagnetic Compatibility (EMC) testing of the Device was performed using the test standard IEC 60601-1-2:2014: *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests*. Testing concluded that the Device met all test requirements for EMC.

Performance Testing-Bench

Mechanical testing was performed to confirm the functionality of key process parameters were performed. All parameters tested were found to meet acceptance criteria established.

Package Transportation Testing

Transportation System Testing Packaging testing of extriCARE 3000 was conducted per the requirements of ISTA 3A. All tested parameters were found to meet acceptance criteria established.

Usability Testing/Human Factors Testing

Usability testing was performed to confirm that the intended user group was found to meet expected use goals.

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, the manufacturer believes that the extriCARE 3000 NPWT Pump is substantially equivalent to the predicate device as described herein.