March 8, 2023

Alleva Medical Ltd
Max Choi
CEO
Suite M-Q, 12th Floor, Kings Wing Plaza 2, 1 On Kwan Street
Shek Mun, New Territories
Hong Kong

Re: K213906
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: November 30, 2021
Received: December 14, 2021

Dear Max Choi:

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 Infection Control
and Plastic 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)*
K213906

Device Name
extriCARE® 1000 Negative Pressure Wound Therapy 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.

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) Summary

[as required by 21 CFR 807.92(c)]

extriCARE 1000 Negative Pressure Wound Therapy System

510(k) K213906

DATE PREPARED:	March 8, 2023
APPLICANT	Alleva Medical Ltd Suite M-Q, 12th Floor, Kings Wing Plaza 2 1 On Kwan Street, Shek Mun, Shatin New Territories, Hong Kong
CONTACT	Mr. Max Choi Chief Executive Officer Phone: +852-3166-7239 Fax: +852-2355-7663 Email: max@allevamedical.com
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:	PICO 14 Single Use Negative Pressure Wound Therapy System (K191760)
REFERENCE DEVICES:	SVED Wound Treatment System (K142916) extriCARE 2400 Negative Pressure Wound Therapy System (K140634)

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.

Device Description:

The extriCARE 1000 Negative Pressure Wound Therapy (NPWT) system consists of a portable, battery-powered 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 is packaged and provided with the following components:

1. extriCARE 1000 Negative Pressure Wound Therapy Pump
2. extriCARE 1000 50cc Collection Canister

The extriCARE 1000 Negative Pressure Wound Therapy (NPWT) Pump accessory that is included in this 510(k) applications and will be commercialized separately is the extriCARE 1000 50cc Collection Canister (additional cannister replacements).

Summary of Technological Characteristics

The extriCARE 1000 pump, similar to its predicate and reference device, operates 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 dressing's underside (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 actual vacuum pressure exceeds target vacuum pressure, a solenoid valve and a check valve will act to allow ambient air into the system and lower the vacuum pressure to the desired level.

Summary of Non-Clinical Testing:

The following non-clinical 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 devices, and conforms to internal standards and regulations.

Electromagnetic Compatibility and Electrical Safety Testing

Standards and Regulations Applied	Results
IEC 60601-1:2005 (Third Edition) + A1:2012(or IEC 60601-1: 2012 reprint)	Passed
IEC 60601-1-2:2014	Passed
IEC 60601-1-6:2010 Edition 3.1, AMD1:2013	Passed
IEC 60601-1-11:2015 Edition 2.0	Passed

Functional Performance Testing

Test Items	Results
Attribute Test	All requirements met
Measurement Test	All requirements met
System and Pneumatic Test	All requirements met
Exudate Removal Test	All requirements met
General Destructive Test	All requirements met
Performance Degradation Test	All requirements met
Hot and Cold Operation Test	All requirements met
Hot and Cold Temperature Test	All requirements met
Transportation Simulation Test	All requirements met

Software Verification and Validation

Software verification and validation activities were completed and there were no unresolved anomalies. The software was determined to be of a “moderate” level of concern, since a failure or latent flaw in the software could directly result in minor injury to the user (and delayed therapy).

Summary of Substantial Equivalence

Selected Features	extriCARE 1000 NPWT System (Subject Device)	Smith & Nephew PICO 14 NPWT System (Predicate) K191760	SVED Wound Treatment System (Reference) K142916	extriCARE 2400 NPWT System (Reference) K140634
Intended Use/ 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	PICO is indicated patients who would benefit from a suction device (NPWT) as it may promote would healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include • chronic, • acute, • traumatic, • subacute and dehisced wounds, • partial-thickness burns • flaps and grafts • closed surgical incisions • ulcers (such as diabetic or pressure)	The Cardinal Health NPWT SVED system is an integrated wound management system, indicated for the application of continual or intermittent negative pressure wound therapy to the wound as the device may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials. The system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The system is intended for use in acute, extended and home care settings.	The extriCARE® NPWT foam kit is intended to be used in conjunction with the extriCARE® 2400 NPWT pump. The extriCARE® 2400 Negative Pressure Wound Therapy System is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The extriCARE Negative Pressure Wound Therapy System 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.

Selected Features	extriCARE 1000 NPWT System (Subject Device)	Smith & Nephew PICO 14 NPWT System (Predicate) K191760	SVED Wound Treatment System (Reference) K142916	extriCARE 2400 NPWT System (Reference) K140634
	incisions The extriCARE 1000 NPWT System is intended for use in healthcare facilities.	PICO 14 Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.		
Contra-indications for Use	▪ 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 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.	▪ Patients with malignancy in the wound bed or margins of the wound (except in palliative care to enhance quality of life) ▪ Previously confirmed and untreated osteomyelitis ▪ Non-enteric and unexplored fistulas ▪ Necrotic tissue with eschar present ▪ Exposed arteries, veins, nerves or organs ▪ Exposed anastomotic sites The PICO 14	The SVED is contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, or necrotic tissue with eschar present. Do not place the NPWT Dressing over exposed blood vessels or organs. The NPWT Dressings are also contraindicated for hydrogen peroxide and solutions which are alcohol based or contain alcohol. It is not recommended to deliver fluids to the thoracic cavity.	▪ 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 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

Selected Features	extriCARE 1000 NPWT System (Subject Device)	Smith & Nephew PICO 14 NPWT System (Predicate) K191760	SVED Wound Treatment System (Reference) K142916	extriCARE 2400 NPWT System (Reference) K140634
	▪ Allergy to silicone dressings and adhesives. ▪ Use of topical products which must be applied more frequently than the dressing change schedule allows	System should not be used for the purposes of: • Emergency airway aspiration • Pleural, mediastinal or chest tube drainage • Surgical suction		be applied more frequently than the dressing change schedule allows
Use	Multi-patient	Single-patient	Multi-patient	Single-patient
Prescription Use	Yes	Yes	Yes	Yes
Vacuum mode	Continuous and Intermittent	Continuous only	Continuous and Intermittent	Continuous and Intermittent
Pressure settings	3, selectable; 80/100/125mmHg	Vary from 60 to 100 mm Hg	70, 120 and 150mmHg	40 – 140mmHg
Flow Rate	~0.5LPM	~0.5LPM	Unknown	About 1.0LPM @ 100mmHg
Canister	50cc	No	300cc and 500cc	100cc and 400cc
Battery	External alkaline, 2 x AA 1.5V	External alkaline, 2 x AA 1.5V	Internal Rechargeable Battery	Internal Rechargeable Lithium battery, 3.7V, 1500mAh
Use barometric environment	800hPa – 1060hPa	800hPa – 1060hPa	50kPa-110kPa	800hPa – 1060hPa

Based on its operating principles, specifications, indications for use, the extriCARE 1000 is substantially equivalent to the predicate devices that were previously cleared. The system does not raise any new risks when compared to the predicate devices.

Conclusions

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 Ltd, believes that the extriCARE 1000 NPWT system performs as well as the predicate device as described herein.