July 26, 2024

NEXA Medical Limited
℅ Robbie Walsh
VP, Quality Assurance & Regulatory Affairs (Official Correspondent for NEXA Medical Limited)
AOTI Limited
Unit 20, Glenrock Business Park
Ballybane
Galway, H91 N23C
Ireland

Re: K241515
Trade/Device Name: NEXA™ NPWT System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 29, 2024
Received: May 29, 2024

Dear Robbie Walsh:

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 Plastic and
Reconstructive Surgery Devices
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and Infection Control Devices
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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)*
K241515

Device Name
NEXA™ NPWT System

Indications for Use *(Describe)*

The NEXA™ Negative Pressure Wound Therapy System (NEXA™ NPWT) is intended for patients who may benefit from the application of negative pressure wound therapy to promote wound healing through the removal of excess exudates, infectious material and the promotion of granulation tissue. It is intended for use in acute, extended and home care settings only when prescribed by a Health Care Professional.

Appropriate wound types include:
• Chronic wounds
• Pressure ulcers
• Diabetic foot ulcers
• Venous leg ulcers
• Acute wounds
• Surgical incisional wounds
• Subacute and dehisced wounds
• Partial thickness burns, flaps and grafts

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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NEXA™ Negative Pressure Wound Therapy System 510(k)

510(k) Summary

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Official Correspondent
Robbie Walsh, AOTI Ltd

Date of Summary
26 July 2024

Device Details

Device Trade Name:	NEXA™ NPWT System
Common Name:	Powered suction pump
Classification Name:	Negative Pressure Wound Therapy Powered Suction Pump
Regulation Number:	21CFR 878.4780
Product Code:	OMP

Legally Marketed Predicate Devices
V.A.C.® Via™ Negative Pressure Wound Therapy System, K132741, Product Code OMP (Predicate Device)
NEXA™ NPWT System, K162610, Product Code OMP (Reference Device)

Device Description
The NEXA™ NPWT (Negative Pressure Wound Therapy) System is intended for patients who may benefit from the use of a suction device to promote wound healing through the removal of excess exudates, infectious material and the promotion of granulation tissue. The device is intended for use in acute, extended and home care settings and only when prescribed by a Health Care Professional.

NEXA™ Negative Pressure Wound Therapy System 510(k)

The system consists of the following components:

1. NEXA™ Device: A portable device that contains a fluid pump and a rechargeable Battery and is supplied with a separate Power Supply and a Carry Case.

2. NEXA™ Fluid Container Pack: A single use polymeric flexible fluid container that stores the exudate removed from the wound.

3. NEXA™ Dressing: Sterile single use wound dressing components that are in contact with the wound tissue and a means of sealing to the peri-wound area. Interconnect tubing includes an integrated negative pressure relief valve that limits the maximum pressure (available in -75mmHg and -125mmHg) able to be applied to the wound.

Utilising a sterile foam dressing placed in the wound, the device operates at negative pressures of -75mmHg or -125mmHg (controlled via dressing selection) to provide continual evacuation of low volumes of exudate from the wound bed into the flexible polymeric fluid container via tubing.

The Fluid Container has a capacity of 120ml which should be changed at least twice a week and includes a disposable pump head.

The dressing should be changed every 48 to 72 hours but no less than 3 times a week. The unit is powered by a 7.4V, 2.6Ah Lithium Ion Battery that is recharged from a 12V plug top power supply. The battery has an integrated charging circuit as well as deep discharge and short circuit protection.

The pressure at the wound site is controlled by mechanical pressure regulation valves. The negative pressure is controlled at a pre-determined level: -75mmHg or -125mmHg, and is set by the selection of the dressing. Two identical valves are included for redundancy purposes.

The size of the NEXA™ Device is (mm): 115 (W) x 115 (H) x 65 (D) and the weight is 0.42kg

<u>Intended Use Comparison</u>
Subject Device: NEXA™ Negative Pressure Wound Management System Intended Use

The NEXA™ Negative Pressure Wound Therapy System (NEXA™ NPWT) is intended for patients who may benefit from the application of negative pressure wound therapy to promote wound healing through the removal of excess exudates, infectious material and the promotion of granulation tissue.
It is intended for use in acute, extended and home care settings only when prescribed by a Health Care Professional.

Appropriate wound types include:
• Chronic wounds
• Pressure ulcers
• Diabetic foot ulcers
• Venous leg ulcers
• Acute wounds
• Surgical incisional wounds
• Subacute and dehisced wounds
• Partial thickness burns, flaps and grafts

Predicate Device: V.A.C.® Via™ Negative Pressure Wound Therapy System Intended Use
The V.A.C. Via™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings.
When used on open wounds, the V.A.C. Via™ Negative Pressure Wound Therapy System 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, the V.A.C. Via™ Negative Pressure Wound Therapy System is intended to manage the environment of surgical incisions that continue to drain following surtured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

Justification of why differences do not constitute a new intended use:
While the wording in the intended use statements is not identical, the intended uses for both devices are equivalent. The intended purpose of the treatment for both devices is equivalent. Both devices are intended for the application of Negative Pressure Wound Therapy to create an environment that promotes wound healing via exudate removal.

NEXA™ Negative Pressure Wound Therapy System 510(k)

Summary of the technological characteristics of the device compared to the predicate device						
Feature	**Subject Device NEXA™ NPWT System**			**Predicate Device V.A.C.® Via™ NPWT System**		
Design	Portable device with moulded plastic enclosure consisting of a rechargeable battery, pump motor and electronic circuitry for controlling pump speed, receiving user inputs and providing alerts to user.			Portable device with moulded plastic enclosure consisting of a rechargeable battery, pump motor and electronic circuitry for controlling pump speed. The predicate device provides additional user controls to select pressure levels and modes of operation.		
Operating Principle	DC powered pump removes fluid from the wound and generates a negative pressure at the wound site which is controlled by mechanical valves			DC powered pump removes fluid from the wound and generates a negative pressure at the wound site which is controlled electronically		
Pump	DC powered, peristaltic pump			DC powered, Diaphragm pump		
Energy Source	Lithium Ion Rechargeable Battery. External power supply (12v DC)			Rechargeable Battery. External power supply (9v DC)		
Software	Software code drives the pump motor and alerts user of a fault condition			Software drives the pump motor, alerts user of a fault condition and controls negative pressure		
Pressure control	Mechanical pressure control valves			Electronic control system		
Pressure range	-125 mmHg and -75 mmHg Selected by prescriber			-125mmHg and -75mmHg User selectable		
Power	Battery and mains connected power supply			Battery and mains connected power supply		
Housing Dimensions	Width 4.1 inches	Length 4.5 inches	Depth 2.5 inches	Width 3.5 inches	Length 8.4 inches	Depth 2.8 inches
Wound fluid container	Flexible fluid container 120ml capacity			Rigid polymeric canister 250ml capacity		
Expected service life	8 weeks			7.5 days		

Dressing System components	Foam: Charcoal coloured polyurethane reticulated foam. Drape: Transparent polyurethane film with adhesive backing. Interconnect tubing: Clear PVC single lumen tubing Phthalate free	Foam: Charcoal coloured polyurethane reticulated foam. Drape: Transparent polyurethane film with adhesive backing. Interconnect tubing: Clear PVC multi lumen tubing contains Phthalates
Direct Contacting Material	Polyurethane hydrophobic reticulated foam. Clear breathable polyurethane medical grade film with acrylic adhesive.	Polyurethane hydrophobic reticulated foam. Clear breathable polyurethane medical grade film with acrylic adhesive.
Indirect Contacting Material	Tubing - Medical grade PVC	Tubing - Medical grade PVC

Performance Data – non-clinical tests

The nonclinical tests submitted in support of this 510(k) submission was a report on a Human Factors Study, completed in line with guidance outlined in FDA Guidance Applying Human Factors and Usability Engineering to Medical-Devices---Guidance-for-Industry-and-Food-and-Drug-Administration-Staff. This study was conducted in a simulated home environment to support the addition of a home use indication to for the NEXA™ NPWT device. The outcome from this study demonstrated that the design/user interface of the device is appropriate for home use and there are proposed updates to the Training Guide, Instructions for Use and Quick Start Guide to support use of the device in a home environment. Consequently, the NEXA™ NPWT device is suitable for use in a home environment and is deemed substantially equivalent to the predicate device, the VAC Via™ NPWT System, which has a home use indication.

The nonclinical tests completed in support of this 510(k) submission were EMC Testing to IEC 60601-1-2:2014+A1:2020 and a Human Factors Study, in line with guidance outlined in FDA Guidance Applying Human Factors and Usability Engineering to Medical-Devices---Guidance-for-Industry-and-Food-and-Drug-Administration-Staff.
These were successfully completed on the NEXA™ NPWT device and the results demonstrate that the device is as safe and performs as well as the predicate device (K132741). This demonstration of substantial equivalence is also based on a review of the subject and predicate devices in the areas of design, materials, energy source and specifications.

Clinical data is not applicable for this submission