DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 8, 2017

Nexa Medical Ltd.
Keith Heaton
Managing Director
Suite 5-6, Willow View, Southfields, Church Lane
Bournemouth, BH22 8TR GB

Re: K162610
Trade/Device Name: Nexa 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 4, 2017
Received: May 8, 2017

Dear Keith Heaton:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162610

Device Name
NEXA NPWT

Indications for Use *(Describe)*

The NEXA NPWT system is intended for patients who may benefit from the application of negative pressure to the wound to promote wound healing through the removal of excess exudate, infectious material and tissue debris.

It is intended for use in long-term care and acute settings only when prescribed by a Health Care Professional.

Appropriate wound types include:
• Chronic wounds
• Pressure ulcers
• Diabetic foot ulcers
• Venous leg ulcers

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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Nexa Medical Limited
NEXA NPWT System 510(k) Summary

510(k) Summary
(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

Submitter Information [21 CFR 807.929(a)(1)]

Submitter's name and address:

Nexa Medical Limited
Suite 5-6 Willow View,
Southfields,
Church Lane,
Bournemouth,
BH22 8TR
UK

FDA Establishment Registration No. To be applied for after marketing clearance is given.

Submitter's telephone number and fax number:

Tel: 011 44 1202 238738
Fax: Nexa Medical Ltd. does not have a fax number

Contact person:

Mr. Keith Heaton, Managing Director

Date this 510(k) summary prepared:

8th June 2017

Name of the device [21 CFR 807.92(a)(2)]

Trade/proprietary name of the device:

NEXA NPWT System

Classification name and number of the device:

FDA Class – II
FDA Product Code: OMP
FDA Classification Name – Powered suction pump
FDA Regulation Number - 21CFR 878.4780

Nexa Medical Limited
NEXA NPWT System 510(k) Summary

Predicate Device [21 CFR 807.92(a)(3)]

Legally marketed predicate devices to which substantial equivalence is claimed:

Device Manufacturer	KCI USA, Inc. (Kinetic Concepts, Inc). San Antonio, TX 78249, US
Device Name	V.A.C.® Via™ NPWT System
FDA 510(k) No.	K132741
Clearance given by FDA to market this device on	November 15th 2013
FDA Device Classification	Class II
FDA Product Code	OMP
FDA Classification Name	Powered suction pump
FDA Regulation Number	21CFR 878.4780

Device Description [21 CFR 807.92(a)(4)]

The NEXA NPWT System is an integrated negative pressure wound management system for use in acute and extended care settings. The system applies a negative pressure to a sealed wound dressing and promotes wound healing through the removal of exudates into a disposable fluid container.

The system consists of the following key components:

1. NEXA Device: A portable device that contains a pump and a rechargeable Battery and is supplied with a 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 able to be applied to the wound and are pre-set and not adjustable by the user.

Nexa Medical Limited
NEXA NPWT System 510(k) Summary

Device Intended Use [21 CFR 807.92(a)(5)]

The NEXA NPWT system is intended for patients who may benefit from the application of negative pressure to the wound to promote wound healing through the removal of excess exudate, infectious material and tissue debris.

It is intended for use in long-term care and acute settings only when prescribed by a Health Care Professional.

Appropriate wound types include:

- Chronic wounds
- Pressure ulcers
- Diabetic foot ulcers
- Venous leg ulcers

Nexa Medical Limited
NEXA NPWT System 510(k) Summary

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]						
Feature	**Candidate Device NEXA NPWT System**			**Predicate Device V.A.C.® Via™ NPWT System**		
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		
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 125ml 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		

Nexa Medical Limited
NEXA NPWT System 510(k) Summary

Performance data [21 CFR 807.92(b)]

Summary of Non Clinical tests undertaken [21 CFR 807.92(b)(1)]

Bench Testing

In order to demonstrate the NEXA NPWT System is substantially equivalent to the Predicate Device V.A.C.® Via™ NPWT System, the following bench testing was undertaken:

- candidate device effectively removes wound fluid in a clinically relevant setting across a range of viscosities and positions
- candidate device generates the stated negative pressure at the wound site
- device alert and warning system works as intended
- duration of the battery life is as stated in the Instructions
- device performs as intended over its stated life cycle
- components with a stated shelf life i.e. dressing components perform as intended over the stated life
- comparative performance testing against the predicate

Bench performance testing was conducted using simulated wound exudates using wound models over a range of clinically relevant conditions.

Bio-compatibility testing

- Of the items included within the NEXA NPWT System, biocompatibility is only applicable to the NPWT Wound Dressing Kits.
- An expert review was completed by an independent test facility that was certified according to EN 45011, ISO 17025, GLP and GMP standards. The purpose of this review was to evaluate the biocompatibility test requirements of the NEXA Medical NPWT Wound Dressing Kits against ISO 10993-1 requirements and FDA guidelines taking into account existing test data, history of use and application of the device.
- Bio-compatibility testing was undertaken with the final materials subjected to production processes.

Nexa Medical Limited
NEXA NPWT System 510(k) Summary

Product testing: Electrical Safety, Usability, EMC & Packaging

- IEC 60601-1 (ed. 3.1) General requirements for basic safety and essential performance (3rd Edition)
- IEC 60601-1-11(ed.1) Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-6(ed.3) General requirements for basic safety and essential performance. Collateral standard. Usability
- IEC 62366 (ed. 1) Medical Devices – Application of usability engineering to medical devices
- EN 60601-1-2:2007 General requirements for safety – Collateral standard: Electromagnetic compatibility – requirements and tests
- ISTA 2 (2011), Vibration and shock for packaged products 150lb (68kg) or less
- BS EN ISO 3744, Acoustic testing

Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]

Not applicable

Nexa Medical Limited
NEXA NPWT System 510(k) Summary

Conclusions drawn regarding substantial equivalence
[21 CFR 807.92(b)(3)]

The results of the nonclinical tests performed demonstrate the performance of the NEXA NPWT is substantially equivalent to the performance of the above named predicate device.
To further establish substantial equivalence to the predicate device, NEXA Medical Limited evaluated the indications for use, materials, technology, and product specifications for the components of the product. As a result of this analysis along with performance testing, NEXA Medical has demonstrated the NEXA NPWT is substantially equivalent to the above named predicate device for its indications for use.

This concludes the 510(k) Summary.