DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 8, 2017

Stortford Medical LLC
Chris Daughtery
President And CEO
295 Princeton Hightstown Road, Unit 321
West Windsor, New Jersey 08550

Re: K161432
Trade/Device Name: MyNeWT Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 5, 2017
Received: January 6, 2017

Dear Chris Daughtery:

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 yours,

Jennifer R. Stevenson -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)*
K161432

Device Name
myNeWT Negative Pressure Wound Therapy System

Indications for Use *(Describe)*

The myNeWT system is indicted for patients who would benefit from Negative Pressure Wound Therapy as it may promote wound healing by removing low to moderate levels (< 37.5 ml/day) of exudate and infectious materials.

Appropriate wound types include:

- Chronic wounds
- Acute, Sub-acute and dehisced wounds
- Traumatic wounds
- Partial thickness burns
- Pressure or venous insufficiency ulcers
- Diabetic ulcers
- Flaps and grafts
- Closed incision sites

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

SUBMITTER

Submitter: Stortford Medical LLC
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Date prepared: 2 February 2017

DEVICE

510(k): K161432
Trade Name: myNeWT Negative Pressure Wound Therapy System
Model number: NWP-001
Common name: Negative Pressure Wound Therapy device
Classification name: Negative Pressure Wound Therapy Powered Suction Pump
Class: II
Product code: OMP
Regulation number: 878.4780

PREDICATE DEVICE

Substantial Equivalent claimed to:

PICO Single Use Negative Pressure Wound Therapy system, Smith and Nephew (510k number K112127 – Primary Predicate), in the basis that both systems are a portable, body worn, disposable Single Use system for patients who have hard to heal wounds. Therapy is accomplished by the electronically controlled pump unit, operating on primary batteries only, and delivering a continuous negative pressure to the wound surface, which draws the exudate into a containment system, creating an environment that promotes wound healing via the removal of low to moderate amounts of exudate and infectious materials from the wound. The device is programmed to run for 7 days after the batteries are inserted, after which the device will not operate and will need to be replaced. Indications for use are similar.

V.A.C Via Negative Pressure Wound Therapy system, KCI USA Inc (510k number K132741 – Additional Predicate), in the basis that both systems are a portable, body worn, Single Use system for patients who have hard to heal wounds. Therapy is accomplished by the electronically controlled pump unit, operating on rechargeable batteries, delivering a negative pressure to the wound surface, which draws the exudate into a containment system, creating an environment that promotes wound healing via the removal of low to moderate amounts of exudate and infectious materials from the wound. The negative pressure level may be varied within set parameters. The device is programmed to run for 7 days, after which the device will not operate and will need to be replaced. Indications for use are similar.

DEVICE DESCRIPTION

The **myNeWT Negative Pressure Wound Therapy System** is a portable, body worn, Single Use system for patients who have hard to heal wounds. Therapy is accomplished by the electronically controlled pump unit delivering a continuous negative pressure at -80 mmHg ±20mmHg to the wound surface, which draws the exudate into a flexible exudate canister, creating an environment that promotes wound healing via the removal of low to moderate amounts (<37.5ml/day) of exudate and infectious materials from the wound. When the canister is full it can be replaced without disturbing the wound bed or the wound dressing. This device is programmed to run for 7 days after the batteries are inserted, after which the device will not operate and will need to be replaced.

The kit consists of:-

- A battery operated vacuum pump, supplied with 2 x AA size Lithium batteries,
- a flexible exudate canister with attached tubing,
- a sterile wound interface kit,
- a carrying bag with straps for the pump and canister.
- User Manual
- Quick Reference Guide – Healthcare Professional
- Quick Reference Guide – Patient

It must be used with a commercially available wound dressing as selected by the Healthcare Professional based on the wound requirements or the physician's prescription. These dressings are **NOT** provided as part of the kit. A list of recommended dressings is provided in the user manual. The dressing must be applied and the myNeWT System set up by a Healthcare Professional skilled in wound care in accordance with the user manual.

The myNeWT System is primarily intended for home healthcare but may be used in other healthcare settings. The patient or caregiver must have the visual and hearing acuity necessary to appropriately respond to notifications from the system and have the sensory and cognitive ability to understand the user manual and directions from a Healthcare Professional pertaining to the proper use of the system.

INDICATIONS FOR USE

Indications for Use

The myNeWT System is indicted for patients who would benefit from Negative Pressure Wound Therapy as it may promote wound healing by removing low to moderate levels (< 37.5 ml/day) of exudate and infectious materials.

Appropriate wound types include:

- Chronic wounds
- Acute, Sub-acute and dehisced wounds
- Traumatic wounds
- Partial thickness burns
- Pressure or venous insufficiency ulcers
- Diabetic ulcers
- Flaps and grafts
- Closed incision sites

Contraindications

The myNeWT System should **NOT** be used in the following conditions:

- Patients with malignancy in the wound bed or margins of the wound.
- Previously confirmed and untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Necrotic tissue with eschar
- Exposed arteries, veins, nerves or organs.
- Anastomotic sites
- Emergency airway aspiration
- Pleural, mediastinal or chest tube drainage
- Surgical suction
- Patients with high (> 37.5 ml/day) exudate flow rates.

The Indications for Use and Contraindications are similar to the predicate devices, and the slight textural variances do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicates. Both the subject and the predicate devices have the same intended use for patients who would benefit from Negative Pressure Wound Therapy as it may promote wound healing by removing low to moderate level of exudate and infectious materials.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The myNeWT System is similar to the predicate devices listed above in function and operating principles to achieve similar results, however the myNeWT System possesses a combination of features that each of the predicate devices incorporate individually. The myNeWT System combines these features to offer greater flexibility in portability, whilst retaining the same clinical benefits.

The subject and predicate devices are based on the following same technological elements:

- A battery operated pneumatic pump to deliver a controlled level of negative pressure (vacuum) to the wound bed of a hard to heal wound
- A controlled level of negative pressure (vacuum) of -60mmHg to -100mmHg nominal
- The pump is software controlled
- A collection device or canister to contain the exudate
- A wound interface to connect the negative pressure to the wound
- A wound dressing cover with medical adhesive (in the myNeWT System, this is supplied by the Healthcare Professional setting up the device from existing wound care products)
- Tubing and connection systems to connect the wound to the vacuum source.
- The system operates for 7 days of therapy only.
- The system is disposable after 7 days of use.

The following technological differences exist between the subject and predicate devices:

- The myNeWT System uses a flexible canister to collect the exudate, the PICO uses a flexible canister combined with the wound interface and the VAC Via uses a rigid canister.
- The myNeWT System allows the Healthcare Professional to select the wound dressing components from a range to cleared medical wound care items, allowing the Healthcare Professional to be able to match the appropriate dressing components to the wound size, shape and location. The predicate devices supply the wound dressing covers, often requiring a range of kits to suit varying wound sizes or shapes, but allows the Healthcare Professional to supply any other wound dressing components required (gauze, skin preps, saline solution etc).
- The myNeWT System and VAC Via have an audible and visual alert to notify the user of system status, the PICO system only has visual alerts.

The myNeWT System provides the safety features required to protect the patient, including high vacuum alert, leak alert, battery status alert, therapy day of use alert and pump error alert.

PERFORMANCE DATA:

Testing has been conducted to verify that the myNeWT System meets the design specifications and to demonstrate substantial equivalence to the predicate devices. The following tests were completed in support of the substantial equivalence of the myNeWT System:

Electrical Safety Standards

The device was tested to AAMI ES 60601-1:2005/R 2012, IEC 60601-1-6: Ed 3.1 2013-10, ANSI/AAMI HA 60601-1-11:2011 and IEC 62366-1:2015

Electromagnetic Compatibility Standards

The device was tested to IEC 60601-1 - 2: Ed 4.0 2014-02 and IEC 60601-1-11: Ed 2.0 2015-01

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation provided as recommended by the FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Biocompatibility Testing

The finished and sterilized wound interface has been tested to ISO10993 and has completed and passed the following biocompatibility testing.

- Cytotoxicity testing to ISO 10993-5,
- Sensitization testing to ISO 10993-10
- Primary skin Irritation testing to ISO 10993-10

Sterility Testing

The wound interface has completed Sterility Validation using Ethylene Oxide to ANSI/AAMI/ISO 11135:2014.

Sterile Packaging Testing

The wound interface, completed and passed packaging testing for terminally sterilized medical devices to BS EN ISO 11607-1:2009 + A1:2014 as detailed below:

- ISTA 2A distribution testing
- 12 month and 36 month accelerated aging
- 12 month real time aging
- 36 months real time aging is ongoing.

Mechanical and Performance Testing

The myNeWT System has undergone verification and validation testing for mechanical and performance parameters:

- Mechanical testing:
  - Compressor life, valve performance, battery life and reverse polarity, pump noise and display visibility, canister mechanical strength, canister exudate containment, cleaning and tube and connector mis-connection.
- Performance testing including:
  - Vacuum levels at the pump
  - Vacuum levels at the wound bed
  - Exudate removal performance
- Stability testing to support the shelf life claims

Usability Testing

The myNeWT System was developed using a usability process that conforms to IEC 62366-1:2015, Edition 1.0 and the FDA Guidance – Applying Human Factors and Usability Engineering to Medical Devices, Feb 02, 2016.

Distribution Testing

The final packed myNeWT kit was subjected to distribution testing in accordance with ISTA Procedure 2A (2011).

Animal Studies

No animal testing was performed on the myNeWT System.

Clinical Studies

Clinical testing was not required to demonstrate the substantial equivalence of the myNeWT System to the predicate devices.

EQUIVALENCY CONCLUSION

The myNeWT System passed all the verification and validation testing, and no new issues of safety or effectiveness have been raised against the predicate devices.

Based on the information provided in the accompanying 510(k), Stortford Medical LLC concludes that the myNeWT System is substantially equivalent to the predicate devices listed above.