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

April 6, 2017

Genadyne Biotechnologies, Inc.
Chien Ming Goh (Andrew)
Vice President, Regulatory Affairs
16 Midland Ave
Hicksville, New York 11801

Re: K161599
Trade/Device Name: Uno 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 18, 2017
Received: February 28, 2017

Dear Mr. Goh:

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,

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)*

K161599

Device Name
Genadyne UNO Negative Pressure Wound Therapy

Indications for Use *(Describe)*
Genadyne UNO is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of low to moderate exudates and infectious material.

Appropriate wound types include:
- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts

Genadyne UNO is a single patient use device.

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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Traditional 510k Summary

Negative Pressure Wound Therapy

Genadyne Biotechnologies, Inc.
16 Midland Ave,
Hicksville, NY 11801

E-mail: Andrew@genadyne.com
(t) 516.217.0100
(f) 516.977.8974

Contact Person: Mr. Chien-Ming GOH (Andrew)

Date Prepared: April 4, 2017

Name of Device

Genadyne UNO Negative Pressure Wound Therapy System

Common or Usual Name

Powered Suction Pump

Classification Name

OMP, Negative Pressure Wound Therapy Powered Suction Pump

21 C.F.R. § 878.4780

Predicate Device

Pico Single Use Negative Pressure Wound Therapy System, K151436

Device Description

The UNO Wound Vacuum System is portable, battery powered wound suction pump with the intention to apply negative pressure to the wound.

Intended Use / Indications for Use

Genadyne UNO is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of low to moderate exudates and infectious material.
Appropriate wound types include:
- Chronic
- Acute

- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts

It is a single patient use device.

Technological Characteristics

Table of Comparison to Predicate Devices:

Comparative Information		
	Predicate Device	**New Device**
Company	Smith and Nephew	Genadyne Biotechnologies
Device Name	Pico Single Use Negative Pressure Wound Therapy System	UNO Single Patient Use Negative Pressure Wound Therapy System
510 (K) Number	K151436	
Technical Data		
Max Vacuum	100 mmHg	125 mmHg
Battery Type	Lithium AA (L91)	Alkaline-Manganese Dioxide AA (QU1500)
Power (Battery)	3V DC	3V DC
Dimensions / Weight	3.5” x 3.5” x 1.0” / <120g	3” x 4.4” x 2.4” / 400g
Accessories		
Canisters	N/A	Two 70 ml disposable canister with a build-in hydrophobic shut off filter for overflow protection
Reusable	No	No
Sterile	Pump, dressing, and secondary fixation strips are sterile	Dressings provided are sterile
Accessories		
		70ml Canisters
Dressings	10cm x 20cm 10cm x 30cm 15cm x 15cm 15cm x 20cm	10cm x 20cm 10cm x 30cm 10cm x 40cm 15cm x 15cm 15cm x 20cm 15cm x 30cm

		20cm x 20cm 20cm x 25cm 25cm x 25cm
	Fixation Strips	Fixation Strips
	Carrying Case	Carrying Case
Indications for Use		
	PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound 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 - Ulcers (such as diabetic or pressure) - Flaps and grafts - Closed surgical incisions PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both hospital and homecare setting	UNO is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of low to moderate exudates and infectious material. Appropriate wound types include: - Chronic - Acute - Traumatic - Subacute and dehisced wounds - Partial-thickness burns - Ulcers (such as diabetic or pressure) - Flaps and grafts Genadyne UNO is a single patient use device.
Contraindications		
-	The Pico is contraindicated in the presence of :	The Genadyne UNO is contraindicated in the presence of:
-	Necrotic tissue with Eschar present	Necrotic tissue with Eschar present
-	Previously confirmed and untreated osteomyelitis.	Untreated osteomyelitis
-	malignancy in the wound bed or margins of the wound (except in palliative care to enhance quality of life)	Malignancy (with exception to enhance quality of life)
-	Exposed arteries, veins, or organs	Exposed arteries, veins, or organs
-	Non-enteric and unexplored fistulas	Non-enteric and unexplored fistulas
-	Anastomotic sites	Anastomotic sites
-	Emergency airway aspiration	Emergency airway aspiration
-	Pleural, mediastinal or chest tube drainage	Pleural, mediastinal or chest tube drainage
-	Surgical suction	Surgical suction
Compliance		
	IEC 60601-1	IEC 60601-1
	IEC 60601-1-2	IEC 60601-1-2

	UL 60601-1	
	Can/CSA C22.2	
Storage / Transport		
	5°C to +25°C (41°F to 77°F)	-18°C to +43°C (0°F to 110°F)
	Relative Humidity 10% to 75 %	Relative Humidity 10% to 95 %
	700 - 1060 mbar Atmospheric pressure	700 – 1060 mbar Atmospheric pressure
Operation	5°C to 35°C (41°F to 95°F)	18°C to 34°C (65°F to 94°F)
	Relative Humidity 10% to 95 %	Relative Humidity 10% to 95 %
	700 - 1060 mbar Atmospheric pressure	700 - 1060 mbar Atmospheric pressure

15. **Discussion of non-clinical and clinical testing**

It appears that the non-clinical results are all showing that it is safe for patient use. The dressing kit, which contains a silicone foam dressing, 4 PU film strips, met the acceptance criteria for biocompatibility testing, and the pump has met the acceptance criteria for all applicable IEC testing. Bench testing was done with in house protocol to establish ensure the performance and outcome of is expected when using together with the device as a system.

The Genadyne UNO has similar design characteristics and provides similar functions to the PICO system. The intended use, indications and instructions for use for the subject and predicate devices are similar. The dressing materials and features are all similar as well. The Genadyne UNO does not raise any new issues of safety and effectiveness. Therefore, it is in our conclusion that the Genadyne UNO is substantially equivalent to the predicate device.

16. **Conclusion & Determination of Substantial Equivalence**

Based on the information presented above, it is concluded that the UNO is substantially equivalent to the predicate device.