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November 30, 2018

Genadyne Biotechnologies, Inc.
Andrew Goh
Vice President
16 Midland Ave
Hicksville, New York 11801

Re: K180840
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: May 22, 2018
Received: May 24, 2018

Dear Andrew 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180840

Device Name
Genadyne UNO Negative Pressure Wound Therapy System

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
- Closed surgical incision

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 K180840

Genadyne UNO Negative Pressure Wound Therapy System

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

Date Prepared: November 29, 2018

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

The primary predicate device is UNO Negative Pressure Wound Therapy System, K161599. The proposed device and the primary predicate device are similar in terms of their technological characteristics.
The secondary predicate device is Pico Single Use Negative Pressure Wound Therapy System, K151436.The proposed device and the secondary predicate device are similar in terms of their indications for use.

Device Description

The UNO Negative Pressure Wound Therapy System is portable, battery powered wound suction pump with the intention to deliver negative pressure wound therapy 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
- Closed surgical incisions

Genadyne UNO is a single patient use device.

Technological Characteristics

Table of Comparison to Predicate Devices:

Comparative Information			
	Secondary Predicate Device	**Primary Predicate Device**	**New Device**
Company	Smith and Nephew	Genadyne Biotechnologies	Genadyne Biotechnologies
Device Name	Pico Single Use Negative Pressure Wound Therapy System	Genadyne UNO Negative Pressure Wound Therapy	Genadyne UNO Negative Pressure Wound Therapy System
510 (K) Number	K151436	K161599	K180840
Technical Data			
Max Vacuum	100 mmHg	125 mmHg	125 mmHg
Battery Type	Lithium AA (L91)	Alkaline-Manganese Dioxide AA (QU1500)	Alkaline-Manganese Dioxide AA (QU1500)
Power (Battery)	3V DC	3V DC	3V DC
Dimensions / Weight	3.5” x 3.5” x 1.0” / <120g	3” x 4.4” x 2.4” / 400g	3” x 4.4” x 2.4” / 400g
Device Lifespan	7 days	24 hours	7 days
Accessories			
Canisters	N/A	Two 70 ml disposable canister with a build-in	Two 70 ml disposable canister with a build-in

		hydrophobic shut off filter for overflow protection	hydrophobic shut off filter for overflow protection
Reusable	No	No	No
Sterile	Dressings are provided sterile	Dressings provided are sterile	Dressings provided are sterile
Accessories			
Dressings	10cm x 20cm 10cm x 30cm 15cm x 15cm 15cm x 20cm	10cm x 10cm 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	10cm x 10cm 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	4 x Fixation Strips	4 x Fixation Strips
	Carrying Case	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	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 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)

	- 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	Genadyne UNO is a single patient use device.	- Flaps and grafts - Closed Surgical Incisions. 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:	The Genadyne UNO is contraindicated in the presence of:
-	Necrotic tissue with Eschar present	Necrotic tissue with Eschar present	Necrotic tissue with Eschar present
-	Previously confirmed and untreated osteomyelitis.	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)	Malignancy (with exception to enhance quality of life)
-	Exposed arteries, veins, or organs	Exposed arteries, veins, or organs	Exposed arteries, veins, or organs
-	Non-enteric and unexplored fistulas	Non-enteric and unexplored fistulas	Non-enteric and unexplored fistulas
-	Anastomotic sites	Anastomotic sites	Anastomotic sites
-	Emergency airway aspiration	Emergency airway aspiration	Emergency airway aspiration
-	Pleural, mediastinal or chest tube drainage	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
	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2

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

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

None of the dressing and device characteristics and technical specs were changed from the last clearance (K161599). Additional biocompatibility testing was performed to support prolonged exposure on breached or compromised surfaces. The dressing is intended to be used for a maximum of 3 days with multiple changes within 7-day device lifespan. A clinical case series from 15 patients with closed surgical incisions were provided as supplementary performance data in support of the safety of the device. The data and results show that the device is biocompatible.

Bench tests were conducted on the subject device to determine its performance. Performance tests include pressure precision, absorbance, and alert functionality. The results were within the acceptable limit of the criteria that were set prior the experiment.

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.