December 14, 2022

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

Re: K221891
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 19, 2022
Received: June 29, 2022

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/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 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 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,

Julie A. Morabito -S

Julie Morabito Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K221891

Device Name
Genadyne UNO Negative Pressure Wound Therapy (NPWT) System

Indications for Use *(Describe)*
Genadyne UNO Negative Pressure Wound Therapy System 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
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed Surgical Incision

Genadyne UNO Negative Pressure Wound Therapy System 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K221891

510k Summary

Date Prepared: April 29, 2022

1.	**Applicant**	Genadyne Biotechnologies, Inc. 16 Midland Ave, Hicksville, NY 11801 T: (516) 487-87878 F: (516) 487-7878 www.genadyne.com
2.	Registration number	2435947
3.	Contact Person	Mr. Chien-Ming Goh Vice president andrew@genadyne.com
4.	Trade/Proprietary Name Including Model Number of Device	Genadyne UNO Negative Pressure Wound Therapy System , U-S0004, U-S0005, U-S0006
5.	Common Name or classification of device	Powered Suction Pump (21 CFR 878.4780, Product Code OMP) Class II
6.	Address of Manufacturing Facility	519 Johnson Ave Bohemia, NY 11716
7.	a. Class in which device has been placed	II
8.	b. Panel	General Plastic Surgery
9.	c. Reason for 510(k) special	Modified plastic housing and change from battery powered to rechargeable lithium ion batteries of current legally device
10.	d. Identification of legally marketed device which we claim substantial equivalence	Genadyne UNO 30 , K190028
11.	Brief Description of the device	The Genadyne UNO Negative Pressure Wound Therapy System is a single patient use Negative Pressure Wound Therapy (NPWT) Unit designed for moderate to low severity wounds. The Genadyne UNO Negative Pressure Wound Therapy System has a pre-determined lifespan. The unit has an interface panel which provides alert and information signals and selectable therapy options. This unit provides negative pressure at either 80 mmHg or 125 mmHg, and has selections of Continuous Mode at 80mmHg/ 30mmHg or 125mmHg / 30mmHg in Variable Mode. The Genadyne UNO Negative Pressure Wound Therapy System Therapy Kits include a therapy unit, 200 ml

		and 300 mL canisters, and sterile dressing kits. Dressing kits and canisters for the Genadyne UNO Negative Pressure Wound Therapy System can be provided separately. The dressing is intended to be used for a maximum of 3 days. Therapy duration of the dressing may be less than indicated if clinical practice or other factors such as wound type, wound size, rate or volume of exudate, orientation of the dressing or environmental conditions, result in more frequent dressing changes. Disposable components of the Genadyne UNO Negative Pressure Wound Therapy System, including the foam dressing and drape, are packaged sterile (Ethylene Oxide) and not made with natural rubber latex. All disposable components of the Genadyne UNO Negative Pressure Wound Therapy System are for single use only. The Genadyne UNO Negative Pressure Wound Therapy System dressings are to be used only with the Genadyne UNO Negative Pressure Wound Therapy System.
12.	Indications for use	The Genadyne Uno NPWT System 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.

13. Comparison of subject and predicate device

	Predicate Device	Subject Device
Company	Genadyne Biotechnologies, Inc.	Genadyne Biotechnologies, Inc.
Device Name	UNO 30	Genadyne UNO Negative Pressure Wound Therapy System
510k number	K190028	K221891
Technical data		
Max Vacuum	125 mmHg	125 mmHg
Battery Type	Alkaline-Manganese Dioxide AA (QU1500)	Lithium Ion Battery
Charger	No	Yes Input: 100VAC-240vAC, 50-60Hz.

		Output: 5V DC, 2A, 10W.
Power Battery	3V DC	3.6V, 1700mAh
Dimensions	3" × 4 3/8" × 2 1/4"	4 3/8 ” x 3 ” x 1 5/8”
Accessories	Contains canisters :- 70 ml disposable canister with a built-in hydrophobic shut off filter for overflow protection	Contains canisters :- 70 ml disposable canister with a built-in hydrophobic shut off filter for overflow protection
Reusable	No	No
Sterile	Dressings are provided Sterile	Dressings are provided Sterile
Accessories		
Dressings	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
	4 X Fixation Strips	4 X Fixation Strips
	Carrying case	Carrying case
Indications for Use	UNO 30 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 - Ulcers (such as diabetic or pressure) - Flaps and grafts - Closed Surgical Incision UNO 30 is a single patient use device.	Genadyne UNO Negative Pressure Wound Therapy System 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 - Ulcers (such as diabetic or pressure) - Flaps and grafts - Closed Surgical Incision Genadyne UNO Negative Pressure Wound Therapy System is a single patient use device.

Contraindications		
	The UNO 30 is contraindicated in the presence of:	The UNO rev B is contraindicated in the presence of:
	Untreated osteomyelitis	Untreated osteomyelitis
	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
	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
Storage/Transport		
	-18°C to +43°C (0°F to 109.4°F)	-18°C to +43°C (0°F to 109.4°F)
Relative Humidity	15% to 95 %	15% to 95 %
Atmospheric Pressure	700 - 1060 mbar	700 - 1060 mbar
Operation		
	18°C to 34°C (65°F to 93.2°F)	18°C to 34°C (65°F to 93.2°F)
Relative Humidity	10% to 95 %	10% to 95 %
Atmospheric pressure	700 - 1060 mbar	700 - 1060 mbar

14. Discussion of Non-Clinical and Clinical Testing

Clinical testing was not performed because as the changes are on the pump itself, which does not have any contact with the patient's wound.

For non-clinical tests, we have submitted in this submission the IEC 60601-1 and IEC 60601-1-2 reports to ensure that the Genadyne UNO Negative Pressure Wound Therapy System has passed and are in compliance with the standard.

15. Conclusion & Determination of Substantial Equivalence

Based on the information presented in the submission, it is concluded that the Genadyne UNO Negative Pressure Wound Therapy System is substantially equivalent to predicate device.