January 15, 2020

Genadyne Biotechnologies
Swara Vashi
Regulatory Affairs Engineer and Official Correspondent
16 Midland Ave
Hicksville, New York 11801

Re: K190028
Trade/Device Name: UNO 30
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: December 16, 2019
Received: December 17, 2019

Dear Swara Vashi:

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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
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)*
K190028

Device Name
UNO 30

Indications for Use *(Describe)*
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.

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.
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(t) 516.487.8787
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Contact Person: Swara Vashi; Mr. Chien-Ming GOH (Andrew)

Date Prepared: January 10, 2020

Name of Device

UNO 30

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, K180840.
The secondary predicate device is Avelle Negative Pressure Wound Therapy System K180205.

Device Description

The UNO 30 is portable, battery powered wound suction pump with the intention to deliver negative pressure wound therapy to the wound. The unit provides negative pressure at either 80mmHg or 125mmHg in continuous mode and 80mmHg/30mmHg or 125mmHg/30mmHg in variable mode. The UNO 30 NPWT system includes dressing and canister.

Intended Use / 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.

Technological Characteristics

Table of Comparison to Predicate Devices:

	Primary Predicate Device	**Secondary Predicate Device**	**Proposed Device**
Company	Genadyne Biotechnologies	ConvaTec Limited	Genadyne Biotechnologies
Device Name	Genadyne UNO Negative Pressure Wound Therapy System	Avelle Negative Pressure Wound Therapy	UNO 30
510 (K) Number	K180840	K180205	K190028
Technical Data			
Max Vacuum	125 mmHg	144 mmHg	125 mmHg
Battery Type	Alkaline-Manganese Dioxide AA (QU1500)	Lithium Batteries	Alkaline-Manganese Dioxide AA (QU1500)
Power (Battery)	3V DC	4.5V DC/Battery	3V DC
Dimensions / Weight	3” x 4.4” x 2.4” / 400g	3” x 3” x 1” / 78g	3” x 4.4” x 2.4” / 400g
Device Lifespan	**7 days**	**30 days**	**30 days**
Accessories			
	Contains canisters:- 70 ml disposable canister with a build-in hydrophobic shut off filter for overflow protection	Contains absorbent wound dressing which is connected via tubing and luer lock fittings and adhesive fixation strips. Does not contain a canister.	Contains canisters :- 70 ml disposable canister with a build-in hydrophobic shut off filter for overflow protection
Reusable	No	No	No

Sterile	Dressings are provided sterile	Dressings are provided sterile	Dressings provided are 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	12cm x 41cm 12cm x 31cm 12cm x 21cm 16cm x 21cm 16cm x 16cm	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	Fixation strips	4 x Fixation Strips
	Carrying Case	Carrying case	Carrying Case
		2 sets of 3 batteries	
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 Incision Genadyne UNO is a single patient use device.	The Avelle NPWT System is indicated for use on patients that would benefit from a Negative Pressure Wound Therapy (NPWT) device as it may promote wound healing via removal of exudate and infectious materials from low to moderately exuding wound such as: -Chronic wound e.g. Leg ulcers -Acute wounds -subacute and dehisced wounds -traumatic wounds -flaps and grafts -surgically closed incision sites. Avelle NPWT System is suitable for use in a hospital, post-acute and home health environment.	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.
Contraindications			
-	The Genadyne UNO is contraindicated in the presence of:	Avelle NPWT System should NOT be used in the following situations:	The UNO 30 is contraindicated in the presence of:

-	Necrotic tissue with Eschar present	Necrotic wounds or wounds with eschar present.	Necrotic tissue with Eschar present
-	Untreated osteomyelitis	Wounds with confirmed and untreated osteomyelitis	Untreated osteomyelitis
-	Malignancy (with exception to enhance quality of life)	Malignant wounds (wound bed and/or wound margins) (except in palliative care to enhance quality of life).	Malignancy (with exception to enhance quality of life)
-	Exposed arteries, veins, or organs	Patients who are sensitive to, or have known allergies to, silicone/acrylic adhesives, sodium carboxymethylcellulose or nylon.	Exposed arteries, veins, or organs
-	Non-enteric and unexplored fistulas	Non-enteric and unexplored fistulas	Non-enteric and unexplored fistulas
-	Anastomotic sites	Anastomosis sites	Anastomotic sites
-	Emergency airway aspiration	For 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	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)	-25 to +70 °C (-13 – 158 °F)	-18°C to +43°C (0°F to 110°F)
Relative Humidity	15% to 95 %	90%	15% to 95 %
Atmospheric pressure	700 - 1060 mbar	700-1060 mbar	700 – 1060 mbar
Operation			
	18°C to 34°C (65°F to 94°F)	5-40°C (41- 104°F)	18°C to 34°C (65°F to 94°F)
Relative Humidity	10% to 95 %	15-90%	Relative Humidity 10% to 95 %
Atmospheric pressure	700 - 1060 mbar	700 to 1060mbar	700 - 1060 mbar Atmospheric pressure

15.	**Discussion of non-clinical and clinical testing**	The pump hardware, dressings, and accessories are unchanged from the predicate (K180840). The pump software was updated to enable a 30-day use-life. Additional bench tests were performed and the software documentation in this submission has been assembled according to the recommendations in the FDA document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, *dated May 11, 2005*. The software Level of Concern has been evaluated and determined to be **Moderate**, and appropriate documentation is included, as recommended by the cited FDA guidance. Bench tests including pressure precision, battery life, absorbance, and alert functionality were conducted to show that the device still functions as appropriately needed during the course of 30 days. It also showed that after 30 days, the unit does not turn on even with new sets of batteries.
16.	**Conclusion & Determination of Substantial Equivalence**	Based on the information presented above, it is concluded that UNO 30 Negative Pressure Wound Therapy System is substantially equivalent to its predicate device.