June 12, 2023

Genadyne Biotechnologies, Inc.
Saiken Ho
Regulatory Affairs Engineer
16 Midland Ave
Hicksville, New York 11801

Re: K221888
Trade/Device Name: Genadyne Hybrid Foam Dressings
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 8, 2023
Received: May 9, 2023

Dear Saiken Ho:

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 A. 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)*
K221888

Device Name
Genadyne Hybrid Foam Dressings

Indications for Use *(Describe)*
Genadyne Hybrid Foam Dressings when used in conjunction with the XLR8+, UNO30 and UNO Plus NPWT System is indicated to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

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
510k : K221888

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Contact Person: Mr. Saiken Ho / Mr. Chien Ming GOH

Date Prepare: June 2, 2023

Name of Device

Genadyne Hybrid Foam Dressings

Common or Usual Name

Negative Pressure Wound Therapy and Accessories

Classification Name

OMP, Negative Pressure Wound Therapy Powered Suction Pump

21 C.F.R. § 878.4780

Predicate Device
The predicate device is the foam dressings of UNO Plus under K210107.

Device Description

The Genadyne Hybrid foam dressings are designed to be used with the Genadyne XLR8+ NPWT (K143726), UNO30 (K190028) and UNO Plus (K210107). The dressing has a layer of silicone that will be placed as a contact layer to the patients wound.

All the dressings are single use disposable items. To help ensure safe and effective use, the Genadyne Hybrid foam dressings are to be used only with the Genadyne supplied devices.

The decision to use clean versus sterile/aseptic technique for wound cleaning is dependent upon wound pathophysiology, physician/clinician preference, and institutional protocol.

Intended Use / Indications for Use

Genadyne Hybrid Foam Dressings when used in conjunction with the XLR8+, UNO30 and UNO Plus NPWT System is indicated to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

Technological Characteristics

Table of Comparison to Predicate Devices:

	New Device	**Predicate Device**
Company	Genadyne Biotechnologies Inc.	Genadyne Biotechnologies Inc.
Device Name	Genadyne Hybrid Foam Dressings	UNO+ Negative Pressure Wound Therapy System
510 (K) Number	K2211888	K210107
Sterile	Dressings provided are sterile	Dressings provided are sterile
Frequency of dressing change	3 days	3 days
Accessories		
Dressings	1. 1 x Hybrid Foam dressing 2. 2 x XLR8 Transparent Film 3. 1 x XLR8 Port Pad	1. 1 x XLR8 PU Reticulated Foam of choice 2. 2 x XLR8 Transparent Film 3. 1 x XLR8 Port Pad
Foam Dressing Sizes	10 x 30 x 0.5 cm	6 x 6 x 2.5 cm (Ref# XF-SFOAM1)
	15 x 20 x 0.5 cm	10 x 15 x 2.0 cm (Ref# XF-MFOAM1)
	15 x 30 x 0.5 cm	7.5 x 10 x 3.3 cm (Ref# XF-SFOAM2)
	10 x 50 x 0.5 cm	12.5 x 18 x 3.3 cm (Ref# XF-MFOAM2)
		Uncoiled Length: 104cm, width: 1.9cm, thickness: 1.6cm (Ref# XF-SPMF1)
Indications for Use	Genadyne Hybrid Foam Dressings when used in conjunction with the XLR8+, UNO30 and UNO Plus NPWT System is indicated to help promote wound healing, through means including	Genadyne UNO Plus (UNO+) Negative Pressure Wound Therapy System is indicated to help promote wound healing, through means including drainage and removal of infectious material or other

	drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

15.	**Discussion of non-clinical and clinical testing**	The proposed device is very similar to the predicate device's foam dressings in terms of its intended use and technological characteristics. Additional bench tests were performed. Bench test was conducted to show that the dressings functions as appropriately when used with the XLR8+, UNO30 and UNO Plus NPWT System. The difference between the predicate and subject device is the additional silicone layer that contacts the wound. It does not raise different questions of safety and effectiveness.
16.	**Conclusion & Determination of Substantial Equivalence**	Genadyne Biotechnologies, Inc. considers the Hybrid Foam Dressings to be as safe as, as effective as and substantially equivalent to the predicate device.