September 27, 2019

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

Re: K182722
Trade/Device Name: XLR8 Abdominal Wound Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP, FTL
Dated: August 28, 2019
Received: August 30, 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,

Cynthia J. Chang, 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)*
K182722

Device Name
XLR8 Abdominal Wound Dressing Kit

Indications for Use *(Describe)*
XLR8 Abdominal Wound Dressing Kit is indicated for use in conjunction with Genadyne NPWT System's XLR8+ for patients who have open abdominal wounds with exposed viscera and organs, including but not limited to patients with abdominal compartment syndrome. XLR8 Abdominal Wound dressing foam is used for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required.
It is intended for use in acute hospital setting(trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.

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

Genadyne Biotechnologies, Inc.
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Contact Person: Swara Vashi, Mr. Chien-Ming GOH (Andrew).

Date Prepared: 27 September 2019

Name of Device: XLR8 Abdominal Wound Dressing Kit

Common or Usual Name: NPWT Dressing Kit

Regulation Name: Powered Suction Pump

Device Class: Class II

Regulation Number: 21 CFR 878.4780

Classification Product Code: OMP

Subsequent Product Code: FTL

Predicate Device: Avance Abdominal Dressing Kit, K161939

Device Description

XLR8 Abdominal Wound dressing is a negative pressure wound therapy device intended to provide negative pressure to the wound bed and transport exudates from the wound. Abdominal Foam is a fully reticulated hydrophobic polyurethane foam made with polyether resin.

XLR8 Abdominal Wound dressing Kit along with Genadyne XLR8+ Negative Pressure Wound therapy Pump and its accessories is a complete negative pressure system for managing open abdomens. This dressing kit is intended for use in acute hospital settings and should ideally be applied in the operating theatre.

The dressing kit consists of one Oval Green Abdominal Foam, one Organ Contact Layer, four transparent dressing, two XLR8 port pad. Each foam is individually packaged in a medical grade Tyvek pouch (1073B Tyvek and a polyester/polyethylene laminate with a 0.375” side and chevron seals.)

XLR8 Abdominal Wound Dressing Foam is for prescription use only.

Indications for Use

XLR8 Abdominal Wound Dressing kit is indicated for use in conjunction with Genadyne NPWT System's XLR8+ for patients who have open abdominal wounds with exposed viscera and organs, including but not limited to patients with abdominal compartment syndrome. XLR8 Abdominal Wound Dressing Foam is used for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required.
It is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.

Technological Characteristics

Table of Comparison to Predicate Devices:

	Predicate Device	Subject Device
Company	Molnlycke Health Care Us, LLC	Genadyne Biotechnologies
Device Name	Avance Abdominal Dressing Kit	XLR8 Abdominal Wound Dressing Kit
510 (K) Number	K161939	K182722
Single Use/ Reusable	Single Use	Single Use
Sterile	Sterile (EtO)	Sterile(EtO)
Indications for Use	The Avance Foam Abdominal Dressing Kit is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required. Its intended use is with patients who have open abdominal wounds with exposed viscera and organs, and including but not limited to patients with abdominal compartment syndrome. It is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre. The dressing kit is intended for use together with the Avance Max NPWT pump and its accessories.	XLR8 Abdominal Wound Dressing Kit is indicated for use in conjunction with Genadyne NPWT System's XLR8+ for patients who have open abdominal wounds with exposed viscera and organs, including but not limited to patients with abdominal compartment syndrome. XLR8 Abdominal Wound dressing Foam is used for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required. It is intended for use in acute hospital setting (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.
Foam Material	Hydrophobic reticulated polyurethane green color foam.	Fully reticulated hydrophobic polyurethane foam.
Kit Components	Avance View Pad Avance Abdominal Foam Avance Organ Contact Layer Avance Transparent Film	XLR8 Port Pad Oval Green Abdominal Foam Organ Contact Layer Transparent Dressing
Kit Component Material	**Avance View Pad**: PVC (polyvinyl chloride) port **Avance Abdominal Foam**: Hydrophobic reticulated polyurethane foam **Avance Organ Contact Layer**: Oval polyurethance foam with fenestrations	**XLR8 Port Pad:** Silicone foam with PVC (polyvinyl chloride) port **Oval Green Abdominal Foam:** fully reticulated hydrophobic polyurethane foam **Organ Contact Layer:** Polyurethane Foam **Transparent Dressing:** polyurethane film with silicone adhesive

	Avance Transparent Film: thin polyurethane film coated with soft silicone adhesive	
Contraindications		
_	Direct positioning of NPWT over exposed organs, large veins and arteries, tendons or nerves. Malignant wounds * Untreated osteomyelitis " Non-enteric or unexplored fistulas * Undebrided wounds with necrotic tissue and eschar present[1]	Untreated osteomyelitis • Direct positioning of NPWT foam over exposed organs, large veins and arteries, anastomotic sites, tendons or nerves. • Necrotic tissue with eschar present • Malignancy in wound (with exception of palliative care to enhance quality of life) • Non-enteric and unexplored fistulas
Packaging	Each component is placed in low density polyethylene pouch with a coated Tyvek header.	Each foam is individually packaged in a medical grade tyvek pouch (1073B Tyvek and a polyester/polyethylene laminate with a 0.375" side and chevron seals.)
Shelf Life	2 years	2 years

[1] (k122132)

Discussion of non-clinical and clinical testing	Biocompatibility tests were performed to support limited contact exposure on breached or compromised surface. The dressing is intended to be used for maximum 24 hours. Bench tests were conducted on the subject device to determine its performance. Performance tests include pressure precision, absorbance, alert and dimension test. The results were within the acceptable limit of the criteria that were set prior the experiment.
Conclusion & Determination of Substantial Equivalence	Based on the information presented above, it is concluded that the XLR8 Abdominal Wound Dressing Kit is substantially equivalent to its predicate device Avance Foam Abdominal Dressing Kit (K161939) with respect to intended use, material and technological characteristics.