



December 23, 2024

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

Re: K233614

Trade/Device Name: Genadyne DUO NPWT
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: April 2, 2024
Received: November 25, 2024

Dear Goh Chien Ming:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu, Ph.D.

Assistant Director

DHT4B: Division of Plastic and

Reconstructive Surgery Devices

OHT4: Office of Surgical and

Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233614

Device Name

Genadyne DUO NPWT

Indications for Use (Describe)

The Genadyne DUO Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy with an instillation option.

- The Genadyne DUO NPWT System, in the absence of instillation is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.
- Instillation therapy is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The Genadyne DUO Negative Pressure Wound Therapy System with and without instillation is indicated for patients with chronic, acute, traumatic, sub acute and dehisced wounds, partial- thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), 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.

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

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510k Summary

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Contact Person: Mr. Chien Ming (Andrew), GOH

Date Prepared: December 20, 2024

Device Name/ Trade Name

Genadyne DUO NPWT

Regulation Name

21 CFR 878.4780, Powered Suction Pump

Product Code

OMP

Classification

Class II

Panel

General and Plastic Surgery

Predicate Device

V.A.C.ULTA Therapy System, K162790

Device Description

The Genadyne DUO NPWT is a Negative Pressure Wound Therapy unit with instillation option. The DUO NPWT features an interface touch panel which provides user selectable therapy modes (continuous mode and variable mode) and multi pressure options from 40 mm Hg to 200 mmHg).

The DUO NPWT is packaged in a box that includes a universal charger, power cable, a user manual and a user carry bag. The dressing kits includes the transparent film dressings, the Genadyne foam dressing and the Genadyne Port. The DUO NPWT is designed to be used with a canister collection system. The canister will have 3 sizes available (600cc, 800cc and 1100cc).

All the dressings and canisters are single use disposable items. To help ensure safe and effective use, the DUO NPWT are to be used only with the Genadyne supplied dressings and canisters.

There is an instillation option on the device for instillation therapy for the patient that requires it. The installation option provides a controlled delivery of topical wound treatment solutions and suspensions over the wound bed. The instill mode consists of NPWT combined with the automatic, controlled delivery and removal of wound treatment solutions to and from the wound bed. It offers a more conducive dressing environment for wound bed management with adjustable target pressure, vacuum time, instill volume, and soaking time. With the adjustable target pressure, negative pressure in mmHg is applied to the wound.

Intended Use / Indications for Use

The DUO Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy with an instillation option.

- The DUO NPWT System, in the absence of instillation is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.
- Instillation therapy is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The DUO Negative Pressure Wound Therapy System with and without instillation is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial- thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts. .

Technological Characteristics

At a high level, the subject device and predicate device are based on the following same technological elements:

- Subject device and predicate device provide the same indicated therapies
- They both have the same technology for delivery of negative pressure and instillation therapies.

The following technological differences exist between the subject and predicate devices:

- They both have different software interface
- They both have different dimensions
- They both use different dressing and disposable canister

Discussion of non-clinical and clinical testing

The subject device is similar to the predicate device in terms of its intended use and technological characteristics. Additional bench tests were performed and the software documentation in this submission has been assembled according to the recommendations in the FDA documents, *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 test per ISO10079-1 was conducted to show that the device still functions as appropriately. Pressure precision test, absorption test, alert capacity test, instill therapy test were performed as part of the bench test.

Conclusion & Determination of Substantial Equivalence

The subject device with design and user interface difference is equivalent to the predicate device.

- There has been no difference to the intended use of the unit.
- There has been no difference to the technology delivering negative pressure and instillation therapy. Performance specifications remains similar.
- All required safety testing and risk assessment performed indicated that the subject device is safe and effective for the intended use.