March 12, 2026

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

Re: K253429
Trade/Device Name: Genadyne ASTRA NPWT
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: February 10, 2026
Received: February 10, 2026

Dear Chien Ming 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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Yu-chieh Chiu -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253429

Device Name
Genadyne ASTRA NPWT

Indications for Use *(Describe)*
Genadyne Astra NPWT System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device can be used for wound management by the removal of excess exudates, infectious material and tissue debris.

Appropriate wound type include:
- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts

For use by healthcare professional and home use. This NPWT System can only be used with approved dressing kits under K233614.

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.

510k Summary

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

Date Prepared: March 12, 2026

Device Name/ Trade Name

Genadyne ASTRA NPWT

Regulation Name

21 CFR 878.4780, Powered Suction Pump

Product Code

OMP

Classification

Class II

Panel

General and Plastic Surgery

Predicate Device
Genadyne UNO Plus (UNO+) Negative Pressure Wound Therapy System, K210107

Device Description

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

NPWT is packaged in a box that includes a universal charger, power cable, a user manual and a user carry bag. The dressing kits (approved under K233614) includes the transparent film dressings, the Genadyne foam dressing and the Genadyne Port. The Genadyne ASTRA NPWT is designed to be used with a canister collection system. The canister will have 3 sizes available (200cc, 400cc and 600cc).

All the dressings and canisters are single use disposable items. To help ensure safe and effective use, the ASTRA NPWT are to be used only with the Genadyne supplied dressings (approved under K233614) and canisters. For our bench test, the ASTRA NPWT was tested with the Genadyne green thick foam dressing kit.

Intended Use / Indications for Use

Genadyne Astra NPWT System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device can be used for wound management by the removal of excess exudates, infectious material and tissue debris.
Appropriate wound type include:
- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts

For use by healthcare professional and home use. This NPWT System can only be used with approved dressing kits under K233614.

Technological Characteristics

	New Device	**Predicate Device**
Company	Genadyne Biotechnologies Inc.	Genadyne Biotechnologies Inc.
Device Name	Astra Negative Pressure Wound Therapy System	UNO+ Negative Pressure Wound Therapy System
510 (K) Number	K253429	K210107
Technical Data		
Max Vacuum	-200mmHg	-125 mmHg
Min Vacuum	-40mmHg	-40mmHg

Patient Population	Adults	Adults
User Interface	5” touchscreen	4 button keypad, visual LED and audit indicators
Dimensions / Weight	5.14 ” x 3.54 ” x 2.92” / 0.82 lbs	4.41” x 3.07” x 1.7” / 220g
Standard safety device	Bacteria / overflow / protection filter	Bacteria / overflow / protection filter
Device Reusability	*Multi Patient Use*	*Multi Patient Use*
Accessories		
Canisters	*200 / 400 / 600ml canister with welded bacteria / overflow / protection filter*	*200 / 300 ml canister with welded bacteria / overflow / protection filter*

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 uses different 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.