October 29, 2026

Nenesupply Co., Ltd.
Chia Hui Chiang
2 F., # 9, Ln. 235, Baoqiao Rd., Xindian District, New Taipei City 231
New Taipei City, 231
TAIWAN

Re: K262125
Trade/Device Name: Nenesupply Venus Handsfree Breast Pump (NBP001-HF)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: September 30, 2026
Received: September 30, 2026

Dear Chia Hui Chiang:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

REBECCA DORSEY -S

For
Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K262125

Device Name
Nenesupply Venus Handsfree Breast Pump (NBP001-HF)

Indications for Use *(Describe)*
The Nenesupply Venus Handsfree Breast Pump (NBP001-HF) is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K262125

1. Submitter Information

Applicant: Nenesupply Co., Ltd.
Address: 2 F., No. 9, Lane 235, Baoqiao Rd., Xindian District, New Taipei City 231, Taiwan (R.O.C.).
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2. Correspondent Information

Contact: Chia Hui Chiang
Tel: +886-77093930 ext 111
Email: lisa@nenesupply.com

3. Date prepared: October 28, 2026

4. Device Information

Device Name:	Nenesupply Venus Handsfree Breast Pump (NBP001-HF)
Common Name:	Powered Breast Pump
Regulation Number:	21 CFR 884.5160
Regulation Name:	Powered Breast Pump
Product Code:	HGX (Pump, Breast, Powered)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Electric Breast Pump
510(k) Number:	K191802
Manufacturer:	Ningbo Huiyoo Baby Products Co. Ltd.

The predicate device has not been subject to a design-related recall.

6. Device Description

The Nenesupply Venus Handsfree Breast Pump (NBP001-HF), is an electrically powered breast pump consisting of the following key components: 2 wearable collection cups which are composed of 2-24mm breast shields, 2 collectors, 2 valves, 2 membranes, 2 sealing caps, a tubing set, 2-21mm nipple inserts, and 2-19mm nipple inserts. The device is powered by rechargeable lithium-ion battery which is charged using the included power cord through the USB port on the pump motor. The breast pump can be operated while plugged into AC power via 5V DC 2.0A USB adaptor.

The motor unit includes a press-button user interface, pump body, and LED display. Pumping can be performed on both breasts (double pumping only). The user interface allows the user to switch from Stimulation, Expression, Mixed Expression, and Deep Expression modes and control the vacuum levels within those modes.

All available modes consist of 9 vacuum levels. The subject device is capable of providing vacuum levels from 30-120 mmHg with cycling rates from 63-111 cycles per minute in stimulation mode, vacuum levels from 32-263 mmHg with cycling rates from 33-67 cycles per minute in expression mode, vacuum levels from 32-263 mmHg with cycling rates from 9-18 cycles per minute in Mixed Expression (short+long) mode, and vacuum

levels from 35-263 mmHg with cycling rates from 23-60 cycles per minute in Deep Expression mode.

The motor unit operates on embedded software. Software updates by end-users are not supported. The subject device is for repeated use by a single user in a home environment. The device is not sterile.

The breast pump expresses milk by creating a seal around the nipple using the flange and applying and releasing suction to the nipple. The milk is collected in a milk collection container. To prevent milk from flowing into the vacuum system, a backflow protection membrane physically separates the milk-contacting pathway from the vacuum system.

All other components (i.e., motor unit/tubing) of the subject device are not in contact with the breast. All milk contacting components (i.e., breast shield, valve, membrane, milk collector) are compliant with 21 CFR 174-179.

7. Indications for Use

The Nenesupply Venus Handsfree Breast Pump (NBP001-HF) is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 1: Comparator Table for Subject and Predicate Devices

	Nenesupply Venus Handsfree Breast Pump (NBP001-HF) K262125 Subject Device	**Electric Breast Pump K191802 Predicate Device**	**Comparison**
Indications for use	The Nenesupply Venus Handsfree Breast Pump (NBP001-HF) is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.	The Electric Breast Pumps are intended to express and collect milk from the breast of a lactating woman.	Similar
Product Code	HGX	HGX	Same
Single User	Yes	Yes	Same
Single/double pump	Double	Single	**Different**
Media separation (backflow protection)	Yes	Yes	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Expression pattern	2-Phase	2-Phase	Same
Power supply	Rechargeable 3.7V 2200 mAh Li-Ion battery	Rechargeable 3.7V 2200 mAh Li-Ion battery	Same
Suction levels (expression)	Double: 32-263 mmHg	20-240 mmHg	**Different**
Suction levels (stimulation)	Double: 30-120 mmHg	20-240 mmHg	**Different**

Suction levels (mixed expression)	Double: 32-263 mmHg	N/A	**Different**
Suction levels (deep expression)	Double: 35-263 mmHg	N/A	**Different**
Cycles per minute (expression)	33-67 cpm	6.5-92.3 cpm	**Different**
Cycles per minute (stimulation)	63-111 cpm	6.5-92.3 cpm	**Different**
Cycles per minute (mixed expression)	9-18 cpm	N/A	**Different**
Cycles per minute (deep expression)	23-60 cpm	N/A	**Different**
Suction levels	9 expression, stimulation, mixed expression, deep expression	6 massage and continuous expression, 9 frequency conversion and normal expression	**Different**
Available modes	Expression, stimulation, mixed expression, deep expression	Massage and continuous expression, frequency conversion and normal expression	**Different**
User Interface	Buttons, LED display	LCD display	Similar
Adjustable Suction Levels	Yes	Yes	Same
Mobile Application	No	No	Same
Design	Tabletop	Tabletop	Same

The indications for use of the subject and predicate device are comparable, and they have the same intended use (i.e., for collection of breast milk from the breasts of lactating women).

The subject and predicate devices have similar technological features, including tabletop design, available vacuum levels, power supply, and user interface. However, as shown in the table above, there are technological differences between the subject and predicate device, including different overall vacuum/cycle specifications, double pumping operation, and available modes. The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility information was provided in accordance with the 2023 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process."* The following tests were conducted on the subject device:

- Cytotoxicity (ISO 10993-5:2009)
- Skin Sensitization (ISO 10993-10:2010)
- Skin Irritation (ISO 10993-23:2021)

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

Electrical Safety
Testing was conducted in accordance with the following standards:

- ANSI/AAMI ES60601- 1:2005/A2:2010 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance),
- IEC 62133-2:2017, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems, and
- IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Electromagnetic Compatibility
Testing was conducted in accordance with the FDA Guidance "Electromagnetic Compatibility (EMC) of Medical Devices," issued June 6, 2022, and IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: "General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests."

Software
Software was evaluated at the Basic Documentation level as recommended in the 2023 FDA guidance document "*Content of Premarket Submissions for Device Software Functions."*

Performance Testing
Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Vacuum level verification testing at each mode/cycle demonstrated that the devices meet mode/cycle specifications.
- Backflow protection testing was conducted to verify liquid does not backflow.
- Use life testing was conducted to demonstrate that the device maintains its specifications throughout the proposed use life.
- Battery performance testing was conducted to demonstrate that the onboard batteries remain functional during the stated battery use-life.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.

10. Conclusion

The results of the performance testing described above demonstrate that the Nenesupply Venus Handsfree Breast Pump (NBP001-HF) is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device.