October 22, 2025

Ningbo Youhe Electrical Appliance Technology Co., Ltd
% Linda Li
Official Correspondent
Huaxiajiamei (Beijing) Information Consulting Co.,LTD
B2 Floor, Zhongguancun Dongsheng Science and Technology Park
No. 66 Xixiaolu Road, Haidian District
Beijing, 100192
CHINA

Re: K251977
Trade/Device Name: electric breast pump (FZ-P8); electric breast pump (YH-P8); electric breast pump (YH-P8X)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: ss II
Product Code: HGX
Dated: September 22, 2025
Received: September 22, 2025

Dear Linda Li:

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.

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,

Monica D. Garcia -S

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)*
K251977

Device Name
electric breast pump (FZ-P8); electric breast pump (YH-P8); electric breast pump (YH-P8X)

Indications for Use *(Describe)*
The electric breast pump (models FZ-P8, YH-P8, YH-P8X) is a wearable electric breast pump intended to express milk from lactating women in order to collect milk from their breasts. The device 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary – K251977

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: October 21, 2025

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Ningbo Youhe Electrical Appliance Technology Co., Ltd
Address:	567# Xintang Road, Fuhai Town, Cixi City, Zhejiang Province, China 315322
Contact person:	Hua Haifeng
Title:	PM
E-mail:	haifeng@youha.com
Tel:	86-15990294120

2. Device Identification

Trade/Device Name:	electric breast pump (models FZ-P8, YH-P8, YH-P8X)
Common name:	Powered Breast Pump
Regulation Number:	21 CFR 884.5160
Regulation Name:	Powered Breast Pump
Regulation Class:	Class II
Product Code:	HGX (Pump, Breast, Powered)

3. Predicate Device

510(K) number:	K231785
Trade/Device Name:	Perifit Pump

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

4. Indication for Use

The electric breast pump (models FZ-P8, YH-P8, YH-P8X) is a wearable electric breast pump intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.

5. Device Description

The electric breast pump (models FZ-P8, YH-P8, YH-P8X) is an electrical wearable breast pump powered by a rechargeable Li-ion battery. It consists of a Pump, Diaphragm, Cup, Valve, Silicone

breast shield (flange) and dust cap:

The pump is the core component of the electric breast pump. It generates a cyclic negative pressure (vacuum) to simulate a baby's sucking motion, drawing milk from the breast into the collection system. The pump is electrically driven and controlled via a motor and control unit, typically offering adjustable suction levels and mode. The diaphragm separates the milk collection system from the pump mechanism, preventing breast milk from entering the pump motor and tubing. The cup is the container that collects and stores the expressed breast milk. The valve controls the one-way flow of breast milk. It opens and closes in sync with the suction cycles to allow milk to flow into the cup while preventing backflow. The silicone breast shield, also known as the flange, is the part that comes into direct contact with the breast. It creates a seal around the nipple and areola to enable effective suction. The dust cap covers the opening of the breast shield or milk collection port when the electric breast pump is not in use. It prevents dust, dirt, and other contaminants from entering the breast pump

The electric breast pump has 2 (Primary mode and secondary mode) x 3 modes (Massage Mode, Expression Mode, and Mixed Mode), each mode has 10 adjustable levels:

- Massage Mode provides a vacuum range of 40–190 mmHg and a frequency of 52–110 cycles per minute;
- Expression Mode provides a vacuum range of 80-280 mmHg and a frequency of 19–75 cycles per minute;
- Mixed Mode provides a vacuum range of 80-280 mmHg and a frequency of 6–63 cycles per minute.

6. 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.

SE Comparisons	**Subject Device** electric breast pump	**Predicate Device** Perifit Pump K231785	**Similarities/ Differences**
Indication for Use	The electric breast pump (models FZ-P8, YH-P8, YH-P8X) is a wearable electric breast pump intended to	The Perifit Pump is a wearable electric breast pump intended to express milk from lactating women in order to collect milk	Same

SE Comparisons	**Subject Device** electric breast pump	**Predicate Device** Perifit Pump K231785	**Similarities/ Differences**
	express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.	from their breasts. The device is intended for a single user.	
Product code	HGX	HGX	Same
Class	II	II	Same
Patient Population	Lactating Women	Lactating Women	Same
Technical specification			
Backflow Protection	Yes	Yes	Same
Modes	2x3 modes	2 modes	Different
Levels	10 levels	8 Levels	Different
Vacuum range	40 to 280 mmHg	30 to 300 mmHg	Different
Cycle speed	6 to 110 cycles per minute	28 to 120 per minute	Different
Battery	Li-ion battery	Li-ion battery	Same
Material	Pump enclosure: ABS Button: ABS Cup: Propylene Ethylene Copolymer Silicone breast shield: Methyl vinyl polysiloxane Diaphragm: Methyl vinyl polysiloxane Valves:Methyl vinyl polysiloxane	Milk-contacting parts are made of silicone, polypropylene, and Tritan copolyester (bottle only) Pump Outer Housing: PC/ABS plastic	Different
Software	Only Pump operates on embedded software.	Pump operates on embedded software. A smartphone app (optional) may also be used to control the pump	Different

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

The subject and predicate device have different technological characteristics, including differences in the device material, flange sizes, functions of the software, mobile app inclusion, power sources,

suction levels, modes and strength, controls, and cycle speed. The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

8. Non-Clinical Performance Testing

Electrical Safety and Electromagnetic Compatibility

Electrical safety and electromagnetic compatibility testing were conducted in accordance with the following standards:

- ANSI/AAMI ES60601-1:2005/A2:2021: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment 2
- IEC 60601-1-11:2015+ A1:2020: 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
- IEC 60601-1-2:2014+A1:2020: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

Biocompatibility

Biocompatibility information was provided in accordance with the Attachment G of the 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” dated September 2023.

Performance Testing

Additional performance testing was conducted to show that the devices meet their design requirements and performs as intended. The performance tests include:

- Vacuum level and cycle frequency verification testing
- Backflow protection testing
- Battery use life
- Use life testing
- Battery charge and discharge time
- Battery status indicator testing

Software

Software verification and validation was evaluated at the Basic Documentation level as recommended in the 2023 FDA guidance document “Content of Premarket Submissions for Device Software Functions” to ensure all software updates meets the specifications and the intended purpose.

9. Conclusion

The results of the performance testing described above demonstrate that the electric breast pump (models FZ-P8, YH-P8, YH-P8X) is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate devices