December 19, 2025

Guangdong Youmeng Electrical Technology Co., Ltd.
% Boyle Wang
General Manger
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lu Jiazui Rd., Pudong
Shanghai, 200120
CHINA

Re: K252342
Trade/Device Name: Electric Breast Pump (YM-8807, YM-8805, YM-8806, YM-8810)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: November 18, 2025
Received: November 18, 2025

Dear Boyle Wang:

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, PhD
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252342

Device Name
Electric Breast Pump (YM-8807, YM-8805, YM-8806, YM-8810)

Indications for Use *(Describe)*
The Electric Breast Pump (Model YM-8807, YM-8805, YM-8806 and YM-8810) is a powered 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.

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510(k) Summary

K252342

510(k) Summary prepared in accordance with requirements of 21 CFR Part 807.92.

1. Submitter's Information

Name: Guangdong Youmeng Electrical Technology Co.,Ltd.
Address: One of Area A, level 3, Building 2, No. 17, Keyuan 3rd Road, Xiaohuangpu Community, Ronggui Street, Shunde District, Foshan City, Guangdong Province, 528303 China
Tel: +86-13567769890
Contact: Mr. Zongjun Liu

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
Address: Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2. Date of Preparation: December 18, 2025

3. Device Information

Trade name: Electric Breast Pump
(YM-8807, YM-8805, YM-8806, YM-8810)
Common name: Powered Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Product Code: HGX (Pump, Breast, Powered)
Device Class: Class II
Classification Panel: Obstetrics/Gynecology

4. Predicate Device Information

Predicate#
510(k) number: K211024
Trade/Device Name: Electric Breast Pump

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

5. Device Description

The Electric Breast Pump (Models YM-8807, YM-8805, YM-8806 and YM-8810) is a powered breast pump intended to express milk from lactating women in order to collect milk from their breasts. The device is provided non-sterile and is reusable device intended for a single user in home healthcare environment.

The breast pump stimulates lactation and extracts milk from the breasts by creating a seal around the nipple and applying and releasing suction to the breast. The milk is collected in a milk collector. The device uses a diaphragm-type vacuum pump driven by a microprocessor. The microprocessor provides control over vacuum pressure and cycle speed. The motor unit operates on a rechargeable Lithium battery (3.7V/1400mAh). The rechargeable battery can be charged from the external power adaptor specified in the User Manual (not included) through the provided USB charging cable. The user interface features four buttons (power, mode selection, vacuum level increase and decrease) and an LED display (current mode, level, timer and battery status), allowing the user to navigate between modes and adjust the vacuum pressure.

The subject device includes four models that have same working principle and technology but differ in terms of their appearance, components, and materials. All device models have three modes of operation: Stimulation phase, Expression phase, Simulated sucking Phase, with nine levels in each mode. The Stimulation phase provides high cycle frequency and gentle suction, while the Expression phase provided slower cycles with higher vacuum pressures. The Simulated sucking phase provides a combination of the other two phases - two cycles in Expression phase followed by one Stimulation phase cycle, then three Expressions phase cycles followed by two in Stimulation phase to form one cycle.

To prevent milk from flowing into the vacuum system, the milk collection set includes a diaphragm that physically separates the milk-contacting pathway from the vacuum system. All milk contacting components of the device are compliant with 21 CFR 177.

6. Indication for Use Statement

The Electric Breast Pump (Model YM-8807, YM-8805, YM-8806 and YM-8810) is a powered 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.

7. 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.

Item	**Subject Device (** K252342) Electric Breast Pump (Models: YM-8807, YM-8805, YM-8806, YM-8810)	**Predicate Device(** K211024) Electric Breast Pump (Models 918, HF918)	**Comparison**
Regulation	Class II, 21 CFR 884.5160	Class II, 21 CFR 884.5160	Same
Product Code	HGX	HGX	Same
Indications for Use	The Electric Breast Pump (Models: YM-8807, YM-8805, YM-8806, YM-8810) is a powered 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.	The Electric Breast Pump (Models 918, HF918) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Electric Breast Pump is intended for a single user.	Same
User Population	Lactating Women	Lactating Women	Same
Single User	Yes	Yes	Same
Pumping Options	Single and Double Pumping	Single and Double Pumping	Same
Cycling Control	Microcontroller	Microcontroller	Same
Pump Type	Diaphragm	Diaphragm	Same
Back Flow Protection	Yes	Yes	Same
Suction Modes and Suction strength (mmHg)	Stimulation Phase: -80 to -160 (±13) Expression Phase: -80 to -280 (±13) Simulated Sucking Phase: -80/-80 to -160/-280 (±13)	Stimulation mode:-60 to -217.5 (±20) Expression mode:-105 to -285 (±20) Two-in One mode: -75 to -285 (±20) Dual-frequency mode: -67.5 to -277.5 (±20) Simulation mode:-187.5(±20)	**Different**

Cycle Speed (cycle/min)	Stimulation Phase:100 to 120 (±2) Expression Phase: 35 to 75 (±2); Simulated sucking Phase:5 to 13 (±2)	Stimulation mode:39 to 123(±5) Expression mode:24 to 84(±5) Two-in one mode: 59 to 123(±5) Dual-frequency mode: 39 to 85(±5) Simulation mode: 14(±5)	**Different**
Suction Levels	9 levels for all modes	5 levels for Stimulation, 7 levels for expression, Two in one and Dual frequency and 1 level for simulation mode	**Different**
Power Supply	3.7V Li-ion Battery	3.7V Li-ion Battery	Same
User Interface	Power button, mode button, level increase button, level decrease button, LED display	Controls on pump and LED/LCD display	**Different**

The subject and predicate device have similar indications for use statements, and the same intended use. They are both used to express and collect milk from a lactating woman's breast. The differences in technological characteristics between the subject devices and the predicate devices are pumping options, suction levels, suction strength, and cycle speed and user interface. These differences do not raise different questions of safety and effectiveness.

8. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the subject devices met all design specifications to be considered substantially equivalent to the predicate device:

8.1 Electrical Safety and Electromagnetic Compatibility

8.1.1 IEC 60601-1:2005/AMD2:2020, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance

8.1.2 IEC 60601-1-2:2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility

8.1.3 IEC 60601-1-11:2020, 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

8.1.4 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

8.2 Biocompatibility

For all breast contacting components of the device, Biocompatibility testing was conducted in accordance with the 2023 FDA guidance "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". Testing included the following assessments:

8.2.1 Cytotoxicity per ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

8.2.2 Skin Irritation per ISO 10993-23:2021, Biological evaluation of medical devices – Part 23:Tests for irritation

8.2.3 Skin Sensitization per ISO 10993-10:2021, Biological evaluation of medical devices – Part 10:Tests for Skin Sensitization

8.3 Software Verification and Validation

Software verification and validation was conducted at basic documentation level in accordance with 2023 FDA Guidance: Content of Premarket Submissions for Device Software Functions.

8.4 Non-Clinical Performance Testing

Additional non-clinical performance tests were conducted to demonstrate that the device meets its design requirements and performs as intended throughout its proposed service-life:

8.4.1 Vacuum pressure and cycle frequency test for all modes and levels of device operation.

8.4.2 Backflow protection testing to ensure no liquid will backflow into the air inlet.

8.4.3 Battery capacity and battery indicator accuracy test to demonstrate that the battery and battery indicator function as intended during its stated use-life.

8.4.4 Use-life testing

8.4.5 Noise level test

The subject device met the pre-defined acceptance criteria for all the above tests.

9. Conclusion

The results of the performance testing described above demonstrate that Electric Breast Pump ((YM-8807, YM-8805, YM-8806, YM-8810) is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device