December 19, 2025

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

Re: K252754
Trade/Device Name: Wearable Electric Breast Pump (YM-8803)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: November 20, 2025
Received: November 20, 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: 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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252754

Device Name
Wearable Electric Breast Pump(YM-8803)

Indications for Use *(Describe)*
The Wearable electric breast pump (Model: YM-8803) 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 – K252754

In accordance with 21 C.F.R. §807.92(a) the following summary of information is provided:

1.0 Submitter's Information

Name: Guangdong Youmeng Electrical Technology Co.,Ltd.
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Contact: Mr. Zongjun Liu

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
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Telephone: +86-21-50313932
Email: Info@truthful.com.cn

Date Prepared: December 18, 2025

2.0 Device Information

Trade name: Wearable Electric Breast Pump (YM-8803)
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
Panel: Obstetrics/Gynecology

3.0 Predicate Device Information

Manufacturer: Shenzhen Lutejiacheng Technology Co., Ltd.
Trade/Device Name: Momcozy Wearable Electric Breast Pump (Model: S9 Pro, S12 Pro)
510(k) number: K230776

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

4.0 Device Description

The Wearable electric breast pump (Model YM-8803) 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 device is provided not sterile and should be cleaned and disinfected according to the instructions for use.
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 container.

The device uses a diaphragm-type vacuum pump driven by a microprocessor. The microprocessor provides control over vacuum pressure and cycle speed.
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. The motor unit operates on a rechargeable battery. The rechargeable battery can be charged from the external power adaptor specified in IFU (not included) through the provided USB charging cable. The user interface features four buttons and an LED display, allowing the user to navigate between modes and adjust the vacuum pressure.

The subject device has two modes: Stimulation and Expression.

Table 4-1 Working Modes of the Subject Device

Model	Modes	Principle of Operation
YM-8803	Stimulation Phase	Fast pumping mode to stimulate milk flow. The device offers 9 adjustable levels.
	Expression Phase	Slower pumping mode for gentle and efficient milk removal. The device offers 9 adjustable levels.

All milk contacting components of the device are compliant with 21 CFR 177 and 175.

5.0 Indications for Use Statement

The wearable electric breast pump (Model:YM-8803) 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.

6.0 Technological Characteristic Comparison Table

Table 6-1 Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Reference Device
510(k) No.	K252754	K230776	K211024
Manufacturer	Guangdong Youmeng Electrical Technology Co., Ltd.	Shenzhen Lutejiacheng Technology Co., Ltd.	Shantou Huihengqi Electronic Technology Co.,Ltd.
Product Name	Wearable Electric Breast Pump (Model YM-8803)	Momcozy Wearable Electric Breast Pump (Models: S9 Pro, S12 Pro)	Electric Breast Pump (Models 918, HF918)
Regulation No.	CFR 884.5160	CFR 884.5160	CFR 884.5160
Product Code	HGX	HGX	HGX
Classification	Class II	Class II	Class II
Patient Population	Lactating Women	Lactating Women	Lactating Women
Environment of Use	Home Healthcare Environment	Home Healthcare Environment	Home Healthcare Environment
Indications for Use (IFU)	The wearable electric breast pump (Model:YM-8803) 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 Momcozy Wearable Breast Pump (model: S9 Pro,S12 Pro) 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.
Pumping Options	Double	Single	Single and Double
Cycling Control	Microcontroller	Microcontroller	Microcontroller
Back Flow Protection	Yes	Yes	Yes
Suction Modes and Suction strength	Stimulation Phase: -70 to -150 mmHg	S9 Pro: Stimulation Mode -85 to -145 S12 Pro: Stimulation Mode, -65 to -135	Stimulation mode: 918, HF918: 60-217.5 mmHg
	Expression Phase: -80	S9 Pro, S12 Pro:	918, HF918:

	to -280 mmHg	Expression Mode -165 to -285	Expression mode: 105-285mmHg
	/	S12 Pro: Mixed Mode -65 to -285	918, HF918: Two-in One mode: 75-285 mmHg
	/	/	918, HF918: Dual-frequency mode: 67.5-277.5 mmHg
	/	/	918, HF918: Simulation mode: 187.5 mmHg
Suction Levels	9	S9 Pro, S12 Pro: 9	Stimulation mode: 5 levels Expression mode: 7 levels Dual-frequency mode: 7 levels Simulation mode: 1 level Massage mode : N/A
Adjustable suction levels	Yes	Yes	Yes
Flange Size	24mm Inner shield sizes of 21 mm and 27 mm are available and can be purchased separately.	24mm	Not disclosed in the 510(k) summary
Cycle Speed (cycle/min)	Stimulation Phase: 68 to 115 Expression Phase: 34 to 101	S9 Pro: Stimulation mode: 73 to 127 Expression mode: 18 to 56 S12 Pro: Stimulation mode: 73 to 127 Expression mode: 18 to 45 Mixed mode: 8 to 17	918, HF918: Stimulation mode: 39 to 123 Expression mode: 24 to 84 Two-in one mode: 59 to 123 Dual-frequency mode: 39 to 85 Simulation mode: 14 Massage mode : N/A
User Control	On pump body	On pump body	On pump body

Power Supply	3.7V Li-ion Battery and mains powered for charging	DC 3.7V / 1600mAh rechargeable lithium battery	3.7V, Lithium ion battery
Indicators	Yes, LED	Yes, LED	Yes, LED
OTC or Rx	OTC	OTC	OTC

The indications for use of the subject and predicate devices are identical, and they have the same intended use – the expression and collection of breast milk from lactating women.

There are different technological characteristics between the subject and predicate device, including differences in pumping options, suction strength, and cycle speed. These differences do not raise different questions of safety or effectiveness.

7.0 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:

Electrical Safety and Electromagnetic Compatibility:

- IEC 60601-1:2005, AMD1:2012, AMD2:2020, ANSI/AAMI ES60601-1: 2005/A2:2021, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance
- IEC 60601-1-2:2014+A1:2020, ANSI/AAMI/IEC 60601-1-2:2014/A1:2021, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility
- IEC TS 60601-4-2:2024, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-11:2015+AMD1:2020 CSV, ANSI/AAMI HA60601-1-11: 2015&A1:2021, 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 60601-1-6:2010+A1:2013+A2:2020, General requirements for basic safety and essential performance Collateral standard: Usability
- IEC 62133-2:2017 + AMD1:2021, 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

For all breast contacting components of the device, biocompatibility testing was conducted in accordance with the FDA guidance "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" dated September 8, 2023. Testing included the following assessments:

- Cytotoxicity per ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- Skin Irritation per ISO 10993-23:2021, Biological evaluation of medical devices – Part 23: Tests for irritation
- Skin Sensitization per ISO 10993-10:2021, Biological evaluation of medical devices – Part 10: Tests for Skin Sensitization

Software Verification

- Software was evaluated at basic documentation level in accordance with 2023 FDA Guidance: Content of Premarket Submissions for Device Software Functions.

The following non-clinical tests were conducted：

- Vacuum test was performed. All the test results complied with the design specifications of the subject device throughout the use life.
- Backflow testing was conducted to ensure that no liquid will backflow into the motor unit, and therefore no liquid can backflow into the pump motor. The test results showed that there was no backflow during the test.
- Cycle speed of subject devices was tested. All the test results complied with the design specifications of the subject devices throughout the use life.
- Battery Capacity and Battery Indicator Accuracy test were conducted to demonstrate that the battery remains functional during its stated use-life and to demonstrate that the battery status indicator remains functional during its stated battery life.

8.0 Conclusion

The comparison and analysis above demonstrates that the proposed device is as safe and effective as the legally marketed predicate device and supports a determination of substantial equivalence to the predicate device.