January 19, 2024

Guangdong Youmeng Electrical Technology Co., Ltd.
℅ Candice Qiu
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm. 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K232466
Trade/Device Name: Electric Breast Pump Model: YM-8166
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: December 5, 2023
Received: December 21, 2023

Dear Candice Qiu:

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.

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 mhre 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,
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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)*
K232466

Device Name
Electric Breast Pump Model: YM-8166

Indications for Use *(Describe)*
The Electric Breast Pump Model: YM-8166 is 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.

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K232499 510(k) Summary

"510(k) Summary" as required by 21 CFR Part 807.92.

Date Prepared: January 17, 2023

I. Submitter

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II. Device

Name of Device: Electric Breast Pump Model: YM-8166
Common or Usual Name: Powered breast pump
Regulation Name: Powered breast pump
Regulation Number: 21 CFR 884.5160
Regulatory Class: II
Product Code: HGX (Powered, Breast, Pump)

III. Predicate Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Clearance Date
Zhejiang Carebao Co., Ltd.	Wearable Breast Pump (YD-1193, YD-1193S, YD1195, YD-1195S, YD-1196,YD-1198, YD-1199, YD-1196S, YD- 1198S, YD-1199S)	K222782	Jan 13, 2023

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

IV. Device Description

The Electric Breast Pump Model: YM-8166 is an over-the-counter, non-sterile, single-user, powered breast pump intended to be used by lactating women to express and collect milk from their breasts. The device is intended for daily use in a home environment. The device uses a diaphragm-type vacuum pump driven by software embedded in the device to generate suction required to stimulate and express breast milk. The software provides control over vacuum pressure and cycle speed.

The following patient-contacting materials are used in the subject device:

Component name	Material of Component	Body Contact Category	Contact Duration
Electric Breast Pump Model: YM-8166 (Major ingredients)	PP & Silicone	Surface-contacting device: Intact skin	Less than 24 hours

Detailed device specifications can be found in the comparison chart below.

V. Indications for Use

The Electric Breast Pump Model: YM-8166 is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.

VI. Comparison of Technological Characteristics with the Predicate Device

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

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
510(k) Number	K232499	K222782	/
Trade name	Electric Breast Pump Model: YM-8166	Wearable Breast Pump (YD-1193, YD-1193S, YD1195, YD-1195S, YD-1196,YD-1198, YD-1199,	/

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
		YD-1196S, YD- 1198S, YD-1199S)	
Manufacturer	Guangdong Youmeng Electrical Technology Co., Ltd.	Zhejiang Carebao Co., Ltd.	/
Regulation number	21 CFR 884.5160	21 CFR 884.5160	Same
Product code	HGX	HGX	Same
Device classification	Class II	Class II	Same
Indication for use/ Intended use	The Electric Breast Pump Model: YM-8166 is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.	The Wearable Breast Pump is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.	Same
Prescription or OTC	OTC	OTC	Same
Pump Options	Single, Double	Single	Different
Provide Non-sterile	Yes	Yes	Same
Re-usable	Yes	Yes	Same
Direct user contact	Yes	Yes	Same
Backflow Protection	Yes	Yes	Same
Suction Modes	Stimulation Mode, Expression Mode, Pseudo-true Expression Mode, Array Mode, and Single/ double	Stimulation Mode and Expression Mode Mixed Mode	Different

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
	Pumping Mode		
Suction levels	16	9	Different
Adjustable suction levels	Yes	Yes	Same
Vacuum range: Stimulation mode	60-165±20 (mmHg)	YD-1193,YD -1193S, YD-1195,YD-1195S: 36 mmHg to 241 mmHg YD-1196,YD-1198, YD-1199, YD-1196S, YD-1198S, YD-1199S: 37 mmHg to 242 mmHg	Similar
Vacuum range: Expression mode	85-280±20 (mmHg)	YD-1193,YD -1193S, YD-1195,YD-1195S: 69 mmHg to 282 mmHg YD-1196,YD-1198, YD-1199, YD-1196S, YD-1198S, YD-1199S: 71 mmHg to 282 mmHg	Similar
Cycle Speed: Stimulation	Single Suction: 66 to 138±5 cycles/minute Double suction: 64 to 180±5 cycles/minute	37.5 to 150 cycles/minute	Different
Cycle Speed: Expression	Single Suction: 32 to 112±5 cycles/minute Double suction:28 to 132±5 cycles/minute	YD-1193,YD -1193S, YD-1195,YD-1195S: 23 to 72 cycles/minute YD-1196, YD-1198, YD-1199, YD-1196S, YD-1198S, YD-1199S: 24 to 69 cycles/minute	Different
Controls	Power button; Mode adjustment button ; Vacuum level increase/	On/Off button; Mode selection Increase/decrease vacuum button;	Similar

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
	decrease button; Night light button (optional) ; Single/ double pumping change button		
Indicator	Yes. General display	Yes. LED	Same
Power Supply	USB connector (Only for charging) by DC 5 V, 2 A	Li-Ion Battery (internally powered by 3.7Vdc lithium battery or externally powered by 5Vdc USB.)	Same
Materials	Milk collection bottle: PP and PPSU (Optional) Breast shield: Silicone rubber Pump unit: ABS and PC	Milk Container: Polypropylene Flange: Silicone Pump Outer Housing: Acrylonitrile Butadiene Styrene (ABS) plastic	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Same
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 62133-2	AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012 IEC 60601-1-2 IEC 60601-1-11 IEC 62133-2	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Same

The Electric Breast Pump Model: YM-8166 has the same intended use, mode of action and similar operational characteristics as the predicate device. The subject device differs from the predicate device in suction modes, strength, and levels, cycle speed, and a double pumping option. The different technological characteristics between the subject device and the predicate device do not raise different questions of safety and effectiveness.

VII.Summary of Non-Clinical Performance Testing

1) Biocompatibility Testing

The biocompatibility evaluation for the patient-contacting components of the Electric Breast Pump Model: YM-8166 was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 4, 2020", as follows:

- ISO 10993-5:2009, Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices –Part 10: Tests for skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices –Part 23: Tests for skin irritation

The patient-contacting components of the subject device were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed per the following standards:

- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- ANSI AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Medical Electrical Equipment –Part 1: 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 62133-2 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

3) Software Verification and Validation

Software verification and validation consistent with a ***basic level*** of concern per the FDA guidance document “Content of Premarket Submissions for Device Software Functions” dated June 14, 2023. System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met, and all software hazards have been mitigated to acceptable risk levels.

4) Additional Non-Clinical Testing

Suction strength and cycle speed of subject devices were tested. 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 tubing, and therefore no liquid can backflow into the pump motor. The test results showed that there was no backflow during the test.

Battery performance testing was conducted to demonstrate that the battery remains functional during its stated use-life.

Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.

VIII. Conclusions

The results of the performance testing described above demonstrate that the Electric Breast Pump Model: YM-8166 is as safe and effective as the predicate device and supports a determination of substantial equivalence.