October 17, 2024

Fimilla (Shanghai) maternity & baby Articles Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K240218
Trade/Device Name: Electric Breast Pump (F5055)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: September 13, 2024

Dear Diana Hong:

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,
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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.

Submission Number *(if known)*

K240218

Device Name

Electric Breast Pump (F5055)

Indications for Use *(Describe)*

The Electric Breast Pump (F5055) is intended to express milk from lactating women and collect milk from their breast. The device is intended for 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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K240218

1. Date Prepared: 10/16/2024

2. Submitter Information

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3. Correspondent Information Ms. Diana

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4. Device Information

Trade Name: Electric Breast Pump (F5055)
Common Name: Electric Breast Pump
Regulation Name: Powered Breast Pump
Regulatory Class: II;
Product Code: HGX (Pump, Breast, Powered);
Regulation Number: 21 CFR 884.5160;

5. Identification of Predicate Device

Device510(K) Number: K163136
Product Name: Youha electric breast pump
Models: YH-8004, YH-8016, YH-8006IV, YH-8015
The predicate device has not been subject to a design-related recall.

6. Indications for Use:

The Electric Breast Pump (F5055) is intended to express milk from lactating women and collect milk from their breast. The device is intended for single user.

7. Device Description

The Electric Breast Pump (F5055) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Electric Breast Pump (F5055) is intended for a single user. The proposed device is electrically powered and software-controlled. The device operates via a microprocessor-driven air pump, which generates suction on the breast to extract milk.

The proposed device is available in one model, F5055. The product is provided non-sterile and is not to be sterilized by the user prior to use. The device includes a breast shield assembly, bottles, pump unit, tubing, an adapter, and pump unit. The breast shield assembly includes a silicone breast shield and polypropylene breast shield body that contacts the user's breast. The main specifications of the subject device are shown in Table 1.

Table 1 Main specifications of subject device

Model	**F5055**
Pumping option	Single or Double
Operating type	Key panel
Basic functions	Massage mode Expression mode Soothing mode
Power Supply	Li-ion battery and power adapter

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. General Comparison of the Subject and Predicate Device

ITEM	Subject Device	Predicate Device (K163136)	Remark
Product	Electric Breast Pump (F5055)	Youha Electric Breast Pump	/
Product Code	HGX	HGX	Same
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	Same
Class	II	II	Same
Indication for Use	The Electric Breast Pump (F5055) is intended to express milk from lactating women and collect milk from their breast. The device is intended for single user.	The Youha electric breast pump is intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.	Same

Patient Population	Breastfeeding women	Breastfeeding women	Same
Anatomical Sites	Breast	Breast	Same
Direct user contact	Yes	Yes	Same
Sterile	Provided Non-sterile	Provided Non-sterile	Same
Single User	Single Use	Single Use	Same
Re-useable	Yes	Yes	Same
Power Source	AC Adapter or Li-Ion Battery	AC/DC wall converter and Rechargeable	Different

Table 2. Performance Comparison of the Subject and Predicate Device

ITEM	Subject Device	(Predicate Device K163136)	Remark
Product	Electric Breast Pump (F5055)	Youha Electric Breast Pump	/
Pump Type	Diaphragm	Diaphragm	Same
Pumping Options	Single and Double Pumping: F5055	Single and Double Pumping: YH-8004/YH-8016 Single Pumping Only: YH-8006IV/YH-8015	Same

Cycling/Suction Control Mechanism		Microprocessor	Microprocessor	Same
Adjustable Suction levels		Yes	Yes	Same
Suction Levels	Massage mode	F5055: 9	YH8004:6 YH8016:6 YH8015:9 YH8006IV:10	Different
	Expression mode	F5055: 9	YH8004:6 YH8016:6 YH8015:9 YH8006IV:10	
	Soothing mode	F5055: 9	N/A	
Suction Strength		70-280mmHg	34-280mmHg	Different
Cycle speed		20-135 cycles/min	16-122cycles/min	Different
Backflow Protection		Yes	Yes	Same

The subject and predicate device have similar indications for use statements and the same intended use – the expression and collection of breast milk. The technological differences between the subject and predicate devices are the power source, suction levels, suction strength, and cycle speed. These differences do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

- Meets Attachment G recommendations (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" (issued September 2023))

Electrical Safety and Electromagnetic Compatibility

- Testing per IEC 60601-1:2010 + AMD2 : 2 0 2 0 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- Testing per IEC 60601-1-2:2014/AMD1: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- Testing per IEC 60601-1-11:2015/AMD1:2020 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment

Software

- Software documentation and verification in accordance with the FDA Guidance document "Content of Premarket Submissions for Device Software Functions" (June 2023)

Performance Testing

- Suction strength, cycle speed, battery indicator, and backflow testing to demonstrate that the device

met design specifications throughout its stated use life.

10. Conclusion

The results of the performance testing described above demonstrate that the Electric Breast Pump (F5055) is as safe and effective as the predicate device and supports a determination of substantial equivalence.