May 13, 2026

Fimilla (Shanghai) Maternity & Baby Articles Co., Ltd.
℅ Youshan Gong
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center
3101-90, Qianhai Rd.
Shenzhen, Guangdong 518052
CHINA

Re: K254125
Trade/Device Name: Electric Breast Pump (Model: HL-3058 II Pro)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: April 13, 2026
Received: April 13, 2026

Dear Youshan Gong:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K254125

Device Name
Electric Breast Pump (Model: HL-3058 II Pro)

Indications for Use *(Describe)*
The Electric Breast Pump (Model: HL-3058 II Pro) 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.

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510(k) Summary – K254125

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

Date Prepared: May 13, 2026

I. Submitter

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II. Device

Device Name: Electric Breast Pump (Model: HL-3058 II Pro)
Common 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 and Reference Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number
Fimilla (Shanghai) Maternity & Baby Articles Co., Ltd	Electric Breast Pump (HL-3058, F5112)	K252629

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

IV. Device Description

The Electric Breast Pump (Model: HL-3058 II Pro) 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.

Electric Breast Pump (Model: HL-3058 II Pro) also has a warming and massaging function which provides heat to the user's neck for warmth and massage.

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

Model	Contacted Component Name	Materials	Body Contact Category	Contact Duration
HL-3058 II Pro	Breast shield	PP	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: HL-3058 II Pro) is intended to express milk from lactating women and collect milk from their breast. The device is intended for single user.

VI. 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.

Comparison Elements	Subject Device K254125	Predicate Device K252629	Remark
510(k) Number	K254125	K252629	/
Trade name	Electric Breast Pump (Model: HL-3058 II Pro)	Electric Breast Pump (HL-3058, F5112)	/
Manufacturer	Fimilla (Shanghai) Maternity & Baby Articles Co., Ltd	Fimilla (Shanghai) maternity & baby Articles 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: HL-3058 II Pro) is intended to express milk from lactating women and collect milk from their breast. The device is intended for single user.	The Electric Breast Pump (Models: HL-3058, F5112) is intended to express milk from lactating women and collect milk from their breast. The device is intended for single user.	Same
Prescription or OTC	OTC	OTC	Same
Pump Options	Single, Double	Single, Double	Same
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	Expression Mode Empty Mode	Different

Comparison Elements	Subject Device K254125	Predicate Device K252629	Remark
	Expression and empty mode Pressure and empty mode	Hot Function Mode	
Suction levels	9	6	Different
Adjustable suction levels	Yes	Yes	Same
Vacuum range:	Stimulation mode: 40 ±5 mmHg Expression mode: 40 to 280 ±5 mmHg Expression and empty mode: 40 to 260 ±5 mmHg Pressure and empty mode: 40 to 190 ±5 mmHg	Expression mode: 60 to 280 ±5 mmHg Empty mode: 40/60 to 40/280 ±5 mmHg	Different
Cycle Speed:	Stimulation mode: 90 to 180 ±2 cycles/minute Expression mode: 30 to 150 ±2 cycles/minute Expression and empty mode: 10 to 20 ±2 cycles/minute Pressure and empty mode: 16 ±2 cycles/minute	Expression mode: Single Suction: 20 to 75 ±2 cycles/minute Double Suction: 20 to 65 ±2 cycles/minute Empty mode: Single Suction: 20 to 85 ±2 cycles/minute Double Suction: 20 to 75 ±2 cycles/minute	Different

Comparison Elements	Subject Device K254125	Predicate Device K252629	Remark
Controls	Power and mode button, Hot compress function button, Massage function button	Five - dimensional navigation button: Power/Voice button, Mode button, Hot function button, Levels increase/ decrease button	Different
Indicator	None, there is a voice prompt function.	None, there is a voice prompt function.	Same
Power Supply	Li-Ion Battery AC adapter provided	Li-Ion Battery	Same
Materials	Milk collection bottle: PP+TPE Breast shield: PP Pump unit: ABS, PC+ABS, Solid Silicone	Milk collection bottle: PP+TPE Breast shield: PP Pump unit: ABS, PC+ABS, Solid Silicone	Same
Hot compress function	Included (neck warmth only)	Included (neck warmth only)	Same
Neck massage function	Included (vibration for comfort)	Not included	Different
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Same
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC TS 60601-4-2 IEC 60601-1-11 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC TS 60601-4-2 IEC 60601-1-11 IEC 62133-2	Same
Biocompatibility	ISO 10993-5	ISO 10993-5	Same

Comparison Elements	Subject Device K254125	Predicate Device K252629	Remark
	ISO 10993-10 ISO 10993-23	ISO 10993-10 ISO 10993-23	

The indications for use of the subject and predicate device are identical, and both devices have the same intended use (i.e., for collection of breast milk from the breasts of lactating women). The technological differences between the subject and predicate device are the modes, including controls, suction strength, and cycle speed. These differences do not raise different questions of safety and effectiveness.

The subject and predicate device have different technological characteristics, including Vacuum pressure range, suction levels and modes, massage function, cycle speed, and controls. These difference do not raise different questions of safety and effectiveness and can be addressed through performance testing.

VII.Summary of Non-Clinical Performance Testing

1) Biocompatibility Testing

The biocompatibility evaluation for the patient-contacting components of the Electric Breast Pump (Model HL-3058 II Pro) was conducted in accordance with 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.

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
- IEC 60601-1 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 was provided per the FDA 2023 guidance document “Content of Premarket Submissions for Device Software Functions” . 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

Vacuum range 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.

Hot function testing was conducted to ensure the device’s neck hot function remained functional during its stated use-life and the temperature of the neck never exceeded 42 °C.

Massage function testing was conducted to demonstrate the neck massage fnction remained functional during its stated use-life.

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.

Use-life testing was conducted to demonstrate the device maintained it's specifications throughout the use-life of the device.

VIII. Conclusions

The results of the performance testing described above demonstrate that the Electric Breast Pump (Model HL-3058 II Pro) is as safe and effective as the predicate device and supports a determination of substantial equivalence.