



December 23, 2025

Linhejiacheng (Shenzhen) E-commerce Co., Ltd.  
Caitlin Liang  
Official Correspondent  
No. 808, 8F, Hasee Computer Building, Marie Curie Avenue,  
Vanke City Community, Bantian Street, Longgang District  
Shenzhen, Guangdong 518000  
CHINA

Re: K253072  
Trade/Device Name: Paruu Wearable Breast pump (P16, P16-A, P16-B, P16-C,  
P16-D, P20, P9, P10, P10 PRO, P21, P22, P23, P24, P25,  
P26, P27, P28, P29, P30, P20-A, P20-B, P20-C, P20-D)  
Regulation Number: 21 CFR 884.5160  
Regulation Name: Powered Breast Pump  
Regulatory Class: II  
Product Code: HGX  
Dated: November 28, 2025  
Received: November 28, 2025

Dear Caitlin Liang:

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](mailto: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

## Indications for Use

510(k) Number (if known)

K253072

Device Name

Paruu Wearable Breast pump (P16, P16-A, P16-B, P16-C, P16-D, P20, P9, P10, P10 PRO, P21, P22, P23, P24, P25, P26, P27, P28, P29, P30, P20-A, P20-B, P20-C, P20-D)

Indications for Use (Describe)

The Paruu Wearable Breast Pump 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.

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# 510(k) Summary

**K253072**

<b>Contact Details</b>		<b>21 CFR 807.92(a)(1)</b>
Applicant Name	Linhejiacheng (Shenzhen) E-commerce Co., Ltd.	
Applicant Address	No. 808, 8F, Hasee Computer Building, Marie Curie Avenue, Vanke City Community, Bantian Street, Longgang District, Shenzhen, Guangdong, 518000, CHINA Shenzhen 51800 China	
Applicant Contact Telephone	86-755-89698173	
Applicant Contact	Ms. Caitlin Liang	
Applicant Contact Email	regulatory@paruulife.com	

<b>Date of Preparation</b>	<b>21 CFR 807.92(a)(1)</b>
December 22, 2025	

<b>Subject Device Information</b>		<b>21 CFR 807.92(a)(2)</b>
Device Trade Name	Paruu Wearable Breast pump (P16, P16-A, P16-B, P16-C, P16-D, P20, P9, P10, P10 PRO, P21, P22, P23, P24, P25, P26, P27, P28, P29, P30, P20-A, P20-B, P20-C, P20-D)	
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	

<b>Predicate Device Information</b>		<b>21 CFR 807.92(a)(3)</b>
510(k) Number	K241322	
Device Trade Name	Electric Breast Pump ( <b>Model LD-208L</b> , LD-3010L, LD-2010L, LD-3010, LD-2010)	
The predicate device has not been subject to a design-related recall.		

## Device Description

**21 CFR 807.92(a)(4)**

The Paruu Wearable Breast Pump is a powered breast pump intended to be used by lactating women to express and collect milk from their breast 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 breast milk is collected in a milk collector. The device consists of a pump motor (main unit), milk collection set (flange, diaphragm, duckbill valve, milk collector, flange cover) and accessories (flange insert, charging cable). The milk collection set and flange insert can be purchased separately.

The device uses a diaphragm-type vacuum pump driven by a microprocessor. The microprocessor provides control over vacuum pressure and cycle speed. The user interface consists of buttons allowing the user to switch between

modes and control the vacuum pressure levels, and LED display that providing information on current mode, level, timer and battery status.

The device includes 23 different models, and based on their technological characteristics, are divided into two broad categories – P16 series consisting of models P16, P16-A, P16-B, P16-C, P16-D, and P20 series consisting of models P20, P9, P10, P10 PRO, P21, P22, P23, P24, P25, P26, P27, P28, P29, P30, P20-A, P20-B, P20-C, P20-D. The models within each series vary in terms of their external color. All device models include 4 working modes (Stimulation, Expression, Two-in-one and Dual frequency for P16 Series and Stimulation, Expression, Lactation, and Traction for P20 Series) and 12 suction levels for each mode.

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 3.7V rechargeable lithium battery. The rechargeable battery can be charged from the external power adapter (not included with the device) through the provided charging cable. All milk contacting components of the device are compliant with 21 CFR 177.

**Intended Use/Indications for Use**

**21 CFR 807.92(a)(5)**

The Paruu Wearable Breast Pump 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.

**Comparison of Intended Use and Technological Characteristics with the Predicate Device  
21 CFR 807.92(a)(5), 21 CFR 807.92(a)(6)**

<b>Item</b>	<b><u>Subject Device (K253072)</u> <u>Paruu Wearable Breast Pump</u></b>	<b><u>Predicate Device (K241322)</u> <u>Electric Breast Pump</u></b>	<b>Comparison</b>
Model	P16, P16-A, P16-B, P16-C, P16-D, P20, P9, P10, P10 PRO, P21, P22, P23, P24, P25, P26, P27, P28, P29, P30, P20-A, P20-B, P20-C, P20-D	LD-208L	
Product Code	HGX	HGX	Same
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	Same
Regulatory Class	Class II	Class II	Same
Patient Population	Lactating Women	Lactating Women	Same
Indications for use	The Paruu Wearable Breast Pump 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 (Model LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010) is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Electric Breast Pump is intended for a single user.	Similar
Single User	Yes	Yes	Same
Single/double pump	Single	Single or double	Same
Media separation (backflow protection)	Yes	Yes	Same

Cycling control mechanism	Microcontroller	Microcontroller	Same
Suction modes	<p>Models- P16, P16-A, P16-B, P16-C, P16-D</p> <p>4 modes - Stimulation, Expression, Two-in-one, Dual frequency</p> <p>Models - P20, P9, P10, P10 PRO, P21, P22, P23, P24, P25, P26, P27, P28, P29, P30, P20-A, P20-B, P20-C, P20-D</p> <p>4 modes - Stimulation, Expression, Lactation, Traction</p>	<p>4 modes -Stimulate, Expression, Bionic sucking, Variable frequency pumping</p>	Different
Power supply	3.7V Rechargeable lithium battery	3.7V Rechargeable Li-Ion Battery	Similar
Vacuum levels (mmHg)	<p>Models- P16, P16-A, P16-B, P16-C, P16-D</p> <p>Stimulation mode : -20 to -160 (<math>\pm 10</math>)</p> <p>Expression mode : -60 to -260 (<math>\pm 20</math>)</p> <p>Two-in-one mode : -60 to -280 (<math>\pm 20</math>)</p> <p>Dual-frequency mode: -130 to -290 (<math>\pm 20</math>)</p> <p>Models - P20, P9, P10, P10 PRO, P21, P22, P23, P24, P25, P26, P27, P28, P29, P30, P20-A, P20-B, P20-C, P20-D</p> <p>Stimulation mode: -48 to -160 (<math>\pm 20</math>)</p> <p>Expression mode: -89 to -295 (<math>\pm 20</math>)</p> <p>Lactation mode: -70 to -295 (<math>\pm 20</math>)</p> <p>Traction mode : -70 to -295 (<math>\pm 20</math>)</p>	<p>Expression mode: 50-290 <math>\pm 30</math></p> <p>Stimulation mode: 40-100 <math>\pm 30</math></p>	Different
Cycle frequency (Cycles per minute)	<p>Models- P16, P16-A, P16-B, P16-C, P16-D</p> <p>Stimulation mode : 60 to 156 (<math>\pm 5</math>)</p> <p>Expression mode : 24 to 108 (<math>\pm 5</math>)</p> <p>Two-in-one mode : 54 to 108 (<math>\pm 5</math>)</p> <p>Dual-frequency mode : 20 to 60 (<math>\pm 5</math>)</p> <p>Models - P20, P9, P10, P10 PRO, P21, P22, P23, P24, P25, P26, P27, P28, P29, P30, P20-A, P20-B, P20-C, P20-D</p> <p>Stimulation mode: 44 to 40 (<math>\pm 5</math>)</p> <p>Expression mode: 22 to 120 (<math>\pm 5</math>)</p> <p>Lactation mode: 42 to 100 (<math>\pm 5</math>)</p> <p>Traction mode : 15 to 37 (<math>\pm 5</math>)</p>	<p>Expression mode: 20-65 <math>\pm 5</math></p> <p>Stimulation mode: 80-120 <math>\pm 5</math></p>	Different
Maximum vacuum	310/315 mmHg	320 mmHg	Different
Suction levels	12 levels for all modes	<p>9 levels for expression, bionic, variable frequency modes;</p> <p>6 levels for stimulation mode</p>	Different
User Interface	<p>Models - P16, P16-A, P16-B, P16-C, P16-D</p> <p>ON/OFF/Mode selection button, Decrease suction level button, increase suction level button, LED</p>	<p>On-Off switch, mode change button, vacuum adjustment buttons, LED</p>	Different

	<b>Models - P20, P21, P22, P23, P25, P27, P10, P10 PRO, P20-A, P20-B, P20-C, P20-D</b> <b>On/Off &amp; Pause button, Mode switch button, Decrease suction level button, increase suction level button, LED</b>		
Design	Wearable diaphragm pump	Wearable diaphragm pump	Same

The subject and predicate device have similar Indications for Use and the same intended use (i.e., for the collection of breast milk from the breasts of lactating women). The subject and predicate devices have similar technological features, including wearable operation, power supply, and user interface. However, as shown in the table above, there are technological differences between the subject and predicate device, including different overall vacuum/cycle specifications and available suction levels in each mode. The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

**Non-Clinical and/or Clinical Tests Summary**

**21 CFR 807.92(b)**

1) Biocompatibility Testing

The biocompatibility evaluation for the patient-contacting components was conducted in accordance with the 2023 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"", as follows:

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

2) Electrical Safety and EMC

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

- a. ANSI AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- b. 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
- c. ANSI AAMI ES60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility
- d. 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 was conducted consistent with a basic level of documentation per the 2023 FDA 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) 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:

- a. Suction strength and cycle speed testing for all modes and levels of device operation
- b. Backflow protection testing to ensure no liquid will backflow into vacuum path
- c. Battery capacity and Battery Indicator testing to demonstrate that the battery and battery indicator function as intended during its stated use-life
- d. Use-life testing to demonstrate that the device continues to meet its performance specifications throughout the proposed use-life.

#### **Conclusions**

**21 CFR 807.92(b)**

The results of the performance testing described above demonstrate that Paruu Wearable Breast Pump (P16, P16-A, P16-B, P16-C, P16-D, P20, P9, P10, P10 PRO, P21, P22, P23, P24, P25, P26, P27, P28, P29, P30, P20-A, P20-B, P20-C, P20-D) is as safe and effective as the predicate devices and supports a determination of substantial equivalence to the predicate devices.