June 18, 2026

Shenzhen Root Innovation Technology Co., Ltd.
Caitlin Liang
#2-201, Floor 2 Hasee Computer Bldg., # 2 Beier Rd.
Bantian St., Longgang
Shenzhen, 518129
CHINA

Re: K254254
Trade/Device Name: Momcozy Wearable Breast Pump (BP311, BP311-A, BP311-B, BP311-C, BP311-D)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 21, 2026
Received: May 22, 2026

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 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
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)*
K254254

Device Name
Momcozy Wearable Breast Pump (BP311, BP311-A, BP311-B, BP311-C, BP311-D)

Indications for Use *(Describe)*
The Momcozy 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

K254254

Contact Details	**21 CFR 807.92(a)(1)**
Applicant Name	Shenzhen Root Innovation Technology Co., Ltd.
Applicant Address	#2-201, Floor 2 Hasee Computer Building, No. 2 Beier Rd, Bantian Street, Longgang, Shenzhen, 518129, China.
Applicant Contact Telephone	86-755-89698173
Applicant Contact	Ms. Caitlin Liang
Applicant Contact Email	regulatory@momcozy.com

Date of Preparation	**21 CFR 807.92(a)(1)**
June 18, 2026	

Device Name	**21 CFR 807.92(a)(2)**
Device Trade Name	Momcozy Wearable Breast Pump (Model: BP311, BP311-A, BP311-B, BP311-C, BP311-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

Predicate Device Information	**21 CFR 807.92(a)(3)**
510(k) Number	K241322
Device Trade Name	Electric Breast Pump (Model LD-208L, 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 Momcozy 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, silicone valve, milk collector, flange cover) and accessories (flange insert, charging cable). All milk contacting components of the device are compliant with 21 CFR 177. 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 an LED display that provides information on current

mode, level, timer and battery status.

The device includes five different models (BP311, BP311-A, BP311-B, BP311-C, BP311-D) that vary in terms of color and the quantity of silicone valve and flange inserts. All models include three working modes (Stimulation, Expression and Mixed mode) and 9 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.

Intended Use/Indications for Use 21CFR807.92(a)(5)

The Momcozy 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)

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

Item	Subject Device Momcozy Wearable Breast Pump	Predicate Device (K241322) Electric Breast Pump	Comparison
Model	BP311, BP311-A, BP311-B, BP311-C, BP311-D	LD-208L	N/A
Product Code	HGX	HGX	Same
Regulation Number	21CFR 884.5160	21CFR 884.5160	Same
Classification	Class II	Class II	Same
Patient Population	Lactating Women	Lactating Women	Same
Indications for Use (IFU)	The Momcozy 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	Similar
Media separation (backflow protection)	Yes	Yes	Same
Cycling Control mechanism	Microcontroller	Microcontroller	Same
Suction modes	3 modes - Stimulation Mode,	4 modes -Stimulate, Expression,	**Different**

	Expression Mode, Mixed Mode	Bionic sucking, Variable frequency pumping	
Suction levels	9 levels.	9 levels for expression, bionic, variable frequency modes; 6 levels for stimulation mode	**Different**
Adjustable Suction Levels	Yes	Yes	Same
Vacuum levels (mmHg)	Stimulation mode: -75 to -150(±20) Expression mode: -125 to -300(±20) Mixed mode: -75 to -300(±20)	Expression mode: 50-290 ± 30 Stimulation mode: 40-100 ± 30	**Different**
Cycle frequency (cycles per minute)	Stimulation mode: 71~89 (±5) Expression mode: 25~62 (±5) Mixed mode: 55~82 (±5)	Expression mode: 20-65 ± 5 Stimulation mode: 80-120 ± 5	**Different**
Maximum vacuum	320 mmHg	320 mmHg	Same
User Interface	Power button, Mode switch button, Increase suction level button, Decrease suction level button, LED	On-Off switch, mode change button, vacuum adjustment buttons, LED	Similar
Power supply	3.7V Rechargeable lithium battery	3.7V Rechargeable Li-Ion Battery	Similar
Design	Wearable diaphragm pump	Wearable diaphragm pump	Same
OTC or Rx	OTC	OTC	Same

The subject and predicate device have similar Indications for Use statements 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, cycling control 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 mode and 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 Performance Testing 21 CFR 807.92(b)

The following performance data were provided in support of the substantial equivalence determination:

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 Momcozy Wearable Breast Pump (BP311, BP311-A, BP311-B, BP311-C, BP311-D) is as safe and effective as the predicate device and supports a determination of substantial equivalence.