June 17, 2026

Shenzhen Root Innovation Technology Co., Ltd.
Baihan Feng
Compliance Engineer
#2-201, Floor 2 Hasee Computer Bldg.,
2 Beier Rd., Bantian St.,Longgang,
Shenzhen, / 518129
CHINA

Re: K260538
Trade/Device Name: Momcozy Wearable Breast Pump (BP420, BP420-A, BP420-B, BP420-C, BP420-D)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 21, 2026
Received: May 21, 2026

Dear Baihan Feng:

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 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,

VASUDHA C. SHUKLA -S

For
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)*
K260538

Device Name
Momcozy Wearable Breast Pump (BP420, BP420-A, BP420-B, BP420-C, BP420-D)

Indications for Use *(Describe)*
The Momcozy Wearable Breast Pump (Model: BP420, BP420-A, BP420-B, BP420-C, BP420-D) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K260538

1. Submitter Information

Applicant: Shenzhen Root Innovation Technology Co., Ltd.
Address: #2-201, Floor 2 Hasee Computer Building, No. 2 Beier Rd, Bantian Street, Longgang, Shenzhen 518129 China
Tel.: 86-755-89698173

2. Correspondent Information

Contact: Mr. Baihan Feng, Compliance Engineer
Shenzhen Root Innovation Technology Co., Ltd.
Email: baihan@rootglobal.net

3. Date prepared: June 17, 2026

4. Device Information

Device Name:	Momcozy Wearable Breast Pump (BP420, BP420-A, BP420-B, BP420-C, BP420-D)
Common Name:	Powered Breast Pump
Regulation Number:	21 CFR 884.5160
Regulation Name:	Powered Breast Pump
Product Code:	HGX (Pump, Breast, Powered)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Electric Breast Pump (LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010)
510(k) Number:	K241322
Manufacturer:	Joytech Healthcare Co., Ltd..

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

6. Device Description

The Momcozy Wearable Breast Pump (BP420, BP420-A, BP420-B, BP420-C, BP420-D) are powered breast pumps intended to be used by lactating women to express and collect milk from their breasts; they are intended for a single user. The devices are powered by lithium-ion battery, utilizing an embedded control program to manage all device functions. The main components of these pumps include: pump motor (main unit), milk collection set (including flange, diaphragm, silicone valve, milk collector, flange cover) and accessories (flange insert, charging cable). The devices use a diaphragm-type vacuum pump driven by a microprocessor.

The breast pump expresses milk by creating a seal around the nipple using the flange and applying and releasing suction to the nipple. The milk is collected in a milk collection container, which can be used for storage. To prevent milk from flowing into the vacuum system, a backflow protection membrane physically separates the milk-contacting pathway from the vacuum system.

The user interface consists of buttons, LED display and mobile app and allows the user to switch from manual modes (stimulation, expression, and mixed mode) and personalized modes (stimulation, expression, mixed mode 1, mixed mode 2) and control the vacuum levels within those modes, warming function and vibration massage function. Personalized modes, accessible via Bluetooth application, allow for expression, mixed mode 1, and mixed mode 2 to adjust between standard, slow, and fast cycle speed settings.

In stimulation mode, the breast pump begins with a quick and short sucking pattern to get milk to start flowing. In expression mode, the breast pump begins with a slow and long sucking pattern for milk expression, sucking more deeply and more slowly. In mixed modes, the breast pump operates in a repeating sequence that combines short and long suction patterns.

All available modes consist of 12 vacuum levels. The devices are capable of providing vacuum levels from 75-160 mmHg with cycling rates from 67-100 cycles per minute in stimulation mode, vacuum levels from 112-295 mmHg with cycling rates from 28-62 cycles per minute in expression mode, 75-295 mmHg with cycling rates from 54-90 cycles per minute in mixed mode. The devices also include personalized modes (accessible via mobile application) which are capable of providing vacuum levels from 75-160 mmHg with cycling rates from 67-100 cycles per minute in stimulation mode, vacuum levels from 112-295 mmHg with cycling rates from 22-65 cycles per minute in expression mode, 75-295 mmHg with cycling rates from 50-91 cycles per minute in mixed mode 1, 75-295 mmHg with cycling rates from 40-84 cycles per minute in mixed mode 2.

The devices are powered by an internal rechargeable lithium-ion polymer battery and charged with the external 5V adapter (not included with the device). The device does not function when charging. The breast pump also includes a mobile app and the device can be wirelessly connected to the mobile app via Bluetooth. Users can operate the device from the app by either selecting preset operating modes or defining a personalized mode. The personalized mode supports up to six sessions, each of which can select its own mode, suction level,functions and duration. The pump remembers the mode and suction level settings. When restarted, it will resume with the same mode and suction level as when it was last turned off. Each mode's suction level setting is also remembered individually and remains consistent during future use. The subject device is for repeated use by a single user in a home and hospital environment. The device is provided non-sterile.

The BP420, BP420-A, BP420-B, BP420-C, BP420-D devices have differences in onboard accessories. Each device model includes both warming and vibration massage function modes, except for BP420-D which only has warming function mode.

All milk contacting components are compliant with 21 CFR 177. Each component can be purchased separately by the user if needed.

7. Indications for Use

The Momcozy Wearable Breast Pump (Model: BP420, BP420-A, BP420-B, BP420-C, BP420-D) 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.

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: Comparator Table for Subject and Predicate Devices

	K260538 Subject Device Momcozy Wearable Breast Pump (Model: BP420, BP420-A, BP420-B, BP420-C, BP420-D)	**K241322 Predicate Device Electric Breast Pump (LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010)**	**Comparison**
Product code	HGX	HGX	Same
Single user device	Yes	Yes	Same
Pump options	Single and double	Single or double	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Backflow protection	Yes	Yes	Same
User interface	LED, Power button; mode switch button, warming/vibration mode button, Increase/decrease vacuum button	On-Off switch, mode change button, vacuum adjustment buttons, LED	**Similar**
Modes	Stimulation, expression, mixed, personalized	Stimulate mode, Expression mode, Bionic sucking mode, Variable frequency pumping mode	**Different**
OTC	Yes	Yes	Same
Suction levels	12	9 expression, bionic, variable frequency; 6 stimulation	**Different**
Vacuum range (mmHg)	Stimulation mode: -75 ±30 to -160 ±30 Expression mode: -112 ±30 to -295 (+30,-25) Mixed mode: -75 ±30 to -295 (+30,-25) Personalized modes: Stimulation mode: -75 ±30 to -160 ±30 Expression mode: -112 ±30 to -295 (+30,-25) Mixed mode 1: -75 ±30 to -295 (+30,-25) Mixed mode 2: -75 ±30 to -295 (+30,-25)	Expression: 50-290±30 Stimulation: 40-100±30	**Different**
Cycle speed (cycles/min)	Stimulation mode: 67±5 to 100±5 Expression mode: 28 ±5 to 62±5 Mixed mode: 54 ±5 to 90 ±5 Personalized modes: Stimulation mode: 67±5 to 100±5 Expression mode: 22±5 to 65±5 Mixed mode 1: 50±5 to 91±5 Mixed mode 2: 40±5 to 84±5	Expression: 20-65 ± 5 Stimulation: 80-120 ± 5	**Different**
Materials	Polyphenylsulfone, silicone, ABS	Silicone diaphragm	**Different**

Power source	3.87V Li-ion battery	3.7V Li-ion battery; 4AA batteries	**Different**
Mobile app	Yes	No	**Different**
Heating element	Yes, 3 levels and less than 41 °C ± 2	No	**Different**
Vibration massage	Yes, 3 levels.	No	**Different**
Design	Wearable	LD-3010L, LD-3010, LD 2010L, LD-2010: Tabletop LD-208L: Wearable	**Different**

The indications for use of the subject and predicate devices are identical, and both devices have the same intended use (i.e., for collection of breast milk from the breasts of lactating women).

The subject and predicate devices have similar technological features, including power supply, inclusion of a mobile application, and maximum vacuum level. However, as shown in the table above, there are technological differences between the subject and predicate devices, including different vacuum pressure/cycle specifications, available modes, and inclusion of heating element and vibration massage. The different technological characteristics of the subject devices, as compared to the predicate device, do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility
Biocompatibility information for patient contacting components were provided in accordance with Attachment G of 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."

Electrical Safety
Testing was conducted in accordance with the following standards:

- ANSI/AAMI ES60601- 1:2005/A2:2010 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance),
- IEC 62133-2:2017, 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, and
- IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: 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.

Electromagnetic Compatibility
Testing was conducted in accordance with the FDA Guidance "Electromagnetic Compatibility (EMC) of Medical Devices," issued June 6, 2022, and IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: "*General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests."*

Software
Software was evaluated at the Basic Documentation level as recommended in the 2023 FDA guidance document "*Content of Premarket Submissions for Device Software Functions."*

Cybersecurity

Cybersecurity documents were provided in accordance with recommendations in the 2025 FDA Guidance document, *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".*

Performance Testing

Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Vacuum level verification testing at each mode/cycle demonstrated that the devices meet mode/cycle specifications.
- Backflow protection testing was conducted to verify liquid does not backflow.
- Use life testing was conducted to demonstrate that the device maintains its specifications throughout the proposed use life.
- Battery performance testing was conducted to demonstrate that the onboard batteries remain functional during the stated battery use-life.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.
- Heating element performance testing demonstrated that device temperature at each level was within acceptable range.
- Vibration massage verification ensured each level was consistent with specifications.

10. Conclusion

The results of the performance testing described above demonstrate that the Momcozy Wearable Breast Pump (BP420, BP420-A, BP420-B, BP420-C, BP420-D) is as safe and effective as the predicate device and supports a determination of substantial equivalence.