October 29, 2025

Shenzhen Root Innovation Technology Co., Ltd.
Wendy Wen
Compliance Engineer
#2-201, Floor 2 Hasee Computer Building, No. 2 Beier Rd,
Bantian Street, Longgang
Shenzhen, 518129
CHINA

Re: K253283
Trade/Device Name: Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP420-, BP431-, BP400-, BP432-, BP434-)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: September 25, 2025
Received: September 29, 2025

Dear Wendy Wen:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253283

Device Name
Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP420-, BP431-, BP400-, BP432-, BP434-)

Indications for Use *(Describe)*
The Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP420-, BP431-, BP400-, BP432-, BP434-) 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.

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510(k) Summary-K253283

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 CHN
Tel: 86-755-89698173

2. Correspondent Information

Contact: Wendy Wen
Compliance Engineer
Shenzhen Root Innovation Technology Co., Ltd.
Email: wendy.wen@rootglobal.net

3. Date prepared: October 28, 2025

4. Device Information

Device Name: Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP434-, BP420-, BP431-, BP432-, BP400-)
Common Name: Powered breast pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Product Code: HGX (Pump, Breast, Powered)
Classification Panel: Obstetrics/Gynecology
Regulatory Class: Class II

5. Predicate Device Information

Device Name: Momcozy Wearable Breast Pump (Model BP223)
510(k) Number: K251394
The predicate device has not been subject to a design related recall.

6. Device Description

The Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP434-, BP420-, BP431-, BP432-, BP400-) is a wearable powered breast pump intended to be used by lactating women to express and collect milk from their breast. The device is a non-sterile reusable device to be used by single user. 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 milk is collected in a milk collector. The device is electrically powered through a rechargeable Lithium battery (3.7V) that can be charged using the USB cable provided with the device.

The subject device includes three operating modes, namely - stimulation mode, expression mode,

and mixed mode, with 15 levels of operation within each mode and a maximum suction of -315mmHg. In stimulation mode, the breast pump begins with a quick and short sucking pattern to get the 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 mode, the breast pump begins with a quick and short sucking pattern, followed by a slow and long sucking pattern. The device features a diaphragm-type vacuum pump driven by a microprocessor. The microprocessor provides control over vacuum pressure and cycle speed during milk expression.

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 device can be connected wirelessly to a mobile device through Bluetooth and be operated through a dedicated mobile application (Mobile flow). By using the application, users can either select one of three preset operating modes or define a personalized mode. The personalized mode supports personalized sessions, each of which can select its own mode, suction level, and duration. Users can also enable a milk overflow reminder function in the app. Pumping output can also be recorded and tracked by users in the app.

The device is available in one or two pumps in a pack to allow for single/double pumping. The subject device includes an LED display that displays information regarding working mode, running time, suction level, battery status, full milk indicator and Bluetooth indicator. The user interface includes on/off/pause switch, mode selection switch, decrease pumping level, increase pumping level and Toggle button to select breast pump direction to left or right. The subject device includes a diaphragm to prevent milk backflow into the vacuum system as well as software based overflow protection.

The device includes a milk collection set that consists of the following: double-sealed flange (Polyphenylsulfone (PPSU) + Silicone), flange insert, diaphragm assembly, duckbill valve assembly, milk collector (Tritan) and main unit pump motor. Each component can be purchased separately by the user if needed.

7. Indications for Use

The Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP420-, BP431-, BP400-, BP432-, BP434-) 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

Item	Subject Device Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP434-, BP420-, BP431-, BP432-, BP400-) K253283	Predicate Device Momcozy Wearable Breast Pump (Model: BP223) K251394	Comment
Product Code	HGX	HGX	Same
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	Same
Regulatory Class	II	II	Same
Indications for Use	The The Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP420-, BP431-, BP400-, BP432-, BP434-) 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 Momcozy Wearable Breast Pump (Model: BP223) 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.	Same
Patient Population	Lactating Women	Lactating women	Same
Single/double pump	Single or double	Single or double	Same
Backflow Protection	Yes	Yes	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
User interface	LED	LED	Same
Modes	Stimulation, expression, mixed	Stimulation, expression, mixed	Same
Suction levels	15	15	Same
Vacuum range (mmHg)	Stimulation mode: -65 to -174 Expression mode: -109 to -305 Mixed mode: -65 to -305 (±30 mmHg, except for -305 which is +30 mmHg and -10 mmHg)	Stimulation mode: -65 to -174 Expression mode: -109 to -305 Mixed mode: -65 to -305 (±30 mmHg, except for -305 which is +30 mmHg and -10 mmHg)	Same
Cycle speed (cycles/min)	Stimulation mode: 54-90 (±5) Expression mode: 25-60 (±5) Mixed mode: 46-84 (±5)	Stimulation mode: 54-90 (±5) Expression mode: 25-60 (±5) Mixed mode: 46-84 (±5)	Same
Power supply	3.7V Li-ion battery	3.7V Li-ion battery	Same
Mobile application	Yes	Yes	Same
Design	Wearable	Wearable	Same

The subject and predicate devices 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 same technological characteristics and differ only in the quantities of device components included in each model (USB Type-C cables, diaphragms, and valves). This difference does not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing:

1) Biocompatibility Testing

The biocompatibility evaluation for the patient-contacting components was leveraged from the predicate device and was 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, including the following:.

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

2) Electrical Safety and EMC

The electrical safety and EMC evaluation for the subject device was leveraged from the predicate device which was conducted 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*
- ANSI AAMI ES60601-1 *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 per the 2023 FDA guidance document "*Content of Premarket Submissions for Device Software Functions*" was leveraged from the predicate device.

4) Cybersecurity

Cybersecurity documentation was leveraged from the predicate device that was in accordance with recommendations in the 2023 FDA Guidance document, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*".

5) Performance and Use Life Verification

The performance testing for the subject device was leveraged from the predicate device

that included the following:

- Vacuum level verification testing at each mode/level
- Backflow protection testing
- Use life testing
- Battery performance and battery status indicator testing

10. Conclusion

The comparison and analysis above demonstrate that Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP434-, BP420-, BP431-, BP432-, BP400-) is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device.