March 9, 2026

Shenzhen Root Innovation Technology Co., Ltd.
Haiyan Wen
Compliance Engineer
2-201, Floor 2 Hasee Computer Bldg., # 2 Beier Rd.
Bantian St., Longgang
Shenzhen, Guangdong 518219
CHINA

Re: K253934
Trade/Device Name: Momcozy Wearable Breast Pump (BP380, BP380-A, BP380-B, BP380-C, M5, M5-A, M5-B, M5-C)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: December 9, 2025
Received: December 9, 2025

Dear Haiyan 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Reginald K. Avery -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253934

Device Name
Momcozy Wearable Breast Pump (BP380, BP380-A, BP380-B, BP380-C, M5, M5-A, M5-B, M5-C)

Indications for Use *(Describe)*
The Momcozy Wearable Breast Pump (Model: BP380,BP380-A,BP380-B,BP380-C,M5,M5-A,M5-B,M5-C) 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) #:K253934

510(k) Summary

Prepared on 2026-03-05

Contact Details 807.92(a)(1)	**21 CFR**
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	Mr. Haiyan Wen
Applicant Contact Email	wendy.wen@rootglobal.net

Device Name 807.92(a)(2)	**21 CFR**
Device Trade Name	Momcozy Wearable Breast Pump (BP380,BP380-A,BP380-B,BP380-C,M5,M5-A,M5-B,M5-C)
Common Name	Powered breast pump
Regulation Name	Powered Breast Pump
Regulation Number	21 CFR 884.5160
Product Code(s)	HGX (Pump, Breast, Powered)
Regulatory Class	II

Legally Marketed Predicate Device 807.92(a)(3)		**21 CFR**
Predicate #	Predicate Device Trade Name	Product Code
K251394	Momcozy Wearable Breast Pump (BP223)	HGX
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 an electrically powered wearable breast pump. There are two product series: Momcozy Wearable Breast Pump M5 series (M5,M5-A,M5-B,M5-C) and Momcozy Wearable Breast Pump BP380 series (BP380,BP380-A,BP380-B,BP380-C).

The differences between M5 series and BP380 series are as follows:
1) BP380 series is equipped with Bluetooth functionality, and can be wirelessly operated via Bluetooth connection to a mobile device
2) M5 series disables the Bluetooth functionality.

The differences between each model in a series is the color of the main unit.

The device is intended to be used by lactating women to express and collect milk from their breast. The device is not sterile. 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 includes stimulation mode, expression mode, and mixed mode. In stimulation mode, the breast pump begins with a quick and short sucking pattern to get your 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 uses a diaphragm-type vacuum pump driven by a microprocessor. The microprocessor provides control over vacuum pressure and cycle speed. 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 operated in single/double pumping modes. 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 a rechargeable battery. The rechargeable battery can be charged from the external power adapter (not included in this device) through the provided charging cable. The user interface consists of buttons and LED display in which the user switches between modes and controls the vacuum pressure.

The BP380 series(BP380,BP380-A,BP380-B,BP380-C) can be wirelessly operated via Bluetooth connection to a mobile device. By using app , users can either select one of three preset operating modes. Available modes include Stimulation, Expression and Mixed.

The devices includes a milk collection set that consists of the following: double-sealed flange, flange insert, diaphragm assembly, duckbill valve assembly, milk collector and main unit pump motor. Each component can be purchased separately by the user if needed. The materials of the milk collection set comply with U.S. food-contact safety testing requirements

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

The Momcozy Wearable Breast Pump (Model: BP380,BP380-A,BP380-B,BP380-C,M5,M5-A,M5-B,M5-C) 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.

Element of Comparison	Subject Device	Predicate Device	Conclusion
Regulation No.	884.5160	884.5160	Same
Product Code	HGX	HGX	Same
Classification	Class II	Class II	Same
Patient Population	Lactating Women	Lactating women	Same
Environment of Use	Home Healthcare Environment	Home Healthcare Environment	Same
Indications for Use (IFU)	The Momcozy Wearable Breast Pump (model: BP380 BP380-A BP380-B BP380-C ; M5 M5-A M5-B M5-C) 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
Pump Options	Single and Double	Single and Double	Same
Cycling	Microcontroller	Microcontroller	Same

Element of Comparison	Subject Device	Predicate Device	Conclusion
Control			
BackFlow Protection	Yes	Yes	Same
Suction Modes	Stimulation Mode, Expression Mode, Mixed Mode	Stimulation Mode, Expression Mode, Mixed Mode	Same
Suction Levels	9	15	Different. Differences in pumping suction level number do not raise different questions of safety and effectiveness
Adjustable suction levels	Yes	Yes	Same
Vacuum Range (mmHg)	Stimulation mode: -75~-145 Expression mode: -120~-285 Mixed mode: -75~-285 （Error：±30mmHg）	Stimulation mode: -65~-174 Expression mode: -109~-305 Mixed mode: -65~-305 （Error：±30 mmHg, except -305 which is +30 mmHg and -10 mmHg）	Different. 1.The minor differences in pumping suction range between subject device and primary predicate device do not raise different questions of safety and effectiveness. 2. the Error setting between subject device and reference Device is similar and it does not do not raise different questions of safety and effectiveness.
Cycle Speed (cycle/min)	Stimulation mode: 50~120(±2) Expression mode: 23~57(±2) Mixed mode: 40~100(±2)	Stimulation mode: 54~90(±5) Expression mode: 25~60(±5) Mixed mode: 46~84(±5)	Different. Differences in available cycle speed do not raise different questions of safety and effectiveness.
Power Supply	3.7V Li-ion Battery	3.7V Li-ion Battery	Same
Indicators	LED	LED	Same
OTC or Rx	OTC	OTC	Same
Mobile Application	Bluetooth connect, IOS and Android App	Bluetooth connect, IOS and Android App	Same

The subject and predicate device have similar indications for use and have the same intended use (i.e. to express milk from lactating women in order to collect milk from their breasts). 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 and/or Clinical Tests Summary & Conclusions 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:

- 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

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

- 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.
- ANSI AAMI ES 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility.
- IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- 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 FDA guidance document "Content of Premarket Submissions for Device Software Functions" dated June 2023. 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

- Suction strength and cycle speed
- Back flow testing
- Battery capacity and Battery Indicator testing
- Device life testing

Conclusions **21 CFR 807.92(b)**

The results of the performance testing described above demonstrate that Momcozy Wearable Breast Pump (BP380,BP380-A,BP380-B,BP380-C,M5,M5-A,M5-B,M5-C) is as safe and effective as the predicate devices and supports a determination of substantial equivalence to the predicate devices.