



September 8, 2025

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

Re: K251394
Trade/Device Name: Momcozy Wearable Breast Pump (BP223)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: Class II
Product Code: HGX
Dated: August 8, 2025
Received: August 8, 2025

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 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, 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)

K251394

Device Name

Momcozy Wearable Breast Pump (BP223)

Indications for Use (Describe)

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.

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 – K251394

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	Mr. Baihan Feng	
Applicant Contact Email	baihan@rootglobal.net	
Date Prepared	September 8, 2025	

Device Name		21 CFR 807.92(a)(2)
Device Trade Name	Momcozy Wearable Breast Pump (BP223)	
Common Name	Powered breast pump	
Regulation Number	884.5160	
Regulation Name	Powered Breast Pump	
Product Code	HGX (Pump, Breast, Powered)	
Regulatory Class	II	

Legally Marketed Predicate Devices		21 CFR 807.92(a)(3)
Predicate #	Predicate Trade Name	Product Code
K241322	Electric Breast Pump (LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010)	HGX
The predicate device has not been subject to a design-related recall.		

Device Description Summary

21 CFR 807.92(a)(4)

The Momcozy Wearable Breast Pump is an electrically powered breast pump to be used in a home environment by a single user. It 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 with a maximum suction of -315mmHg. Each mode has multi-adjustable suction levels. 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.

BP223 can connect wirelessly to a mobile device and be operated through a dedicated mobile application (M9 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.

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 (On/off/Pause, Mode selection, Decrease pumping level Increase pumping level and Toggle button to select breast pump direction to left or right) and an LED display in which the user switches between modes and controls the vacuum pressure.

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.

Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

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

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.

	Momcozy Wearable Breast Pump (BP223) K251394 Subject Device	Electric Breast Pump (Model LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010) K241322 Predicate Device	Comparison
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 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.	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
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	Stimulate, expression, bionic sucking, variable frequency pumping	Different
Suction levels	15	9 expression, bionic, variable frequency; 6 stimulation	Different
Vacuum range (mmHg)	Stimulation: -65 to -174 Expression: -109 to -305 Mixed: -65 to -305 (± 30 mmHg, except -305 which is +30 mmHg and -10 mmHg)	Expression: 50-290 ± 30 Stimulation: 40-100 ± 30	Different
Cycle speed (cycles/min)	Stimulation: 54-90 (± 5) Expression: 25-60 (± 5) Mixed: 46-84 (± 5)	Expression: 20-65 ± 5 Stimulation: 80-120 ± 5	Different
Power supply	3.7V Li-ion battery	LD-3010L, LD-2010L: In: 100-240 VAC, 50/60 Hz, 0.25A Mains out: 5VDC, 1.0A	Different

		Battery out: 3.7VDC, 2,000 mAh LD-3010, LD-2010: In: 100-240 VAC, 50/60 Hz, 0.25A Mains out: 5VDC, 1.0A Battery out: 4 AA batteries LD-208L: In: 100-240 VAC, 50/60 Hz, 0.25A Mains out: 5VDC, 1.0A (only for charging) Battery out: 3.7VDC, 1,200mAh	
Mobile application	Yes	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 similar, 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 expression mode options control mechanism, backflow protection, and device indicators. However, there are technological differences between the subject and predicate device, including different vacuum and cycle specifications, and vacuum levels. 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:

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

4) Cybersecurity

Cybersecurity information was provided in accordance with recommendations in the 2023 FDA Guidance document, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*.

5) Additional Non-Clinical Testing

- Suction strength and cycle speed
- Backflow protection testing
- Battery capacity and Battery Indicator testing
- Use life testing (one year)

Conclusion

The results of the performance testing described above demonstrate that Momcozy Wearable Breast Pump (BP223) is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate devices.