June 9, 2026

Shenzhen TPH Technology Co., Ltd.
Dale WANG
Regulatory Affairs Engineer
Rm. 203, 2nd Floor, 29th Bldg., Lianchuang Technology Park,
21 Bulan Rd., Xialilang Community, Nanwan St., Longgang District
Shenzhen, 518000
China

Re: K260864
Trade/Device Name: Mother's Nature W1 Warming Wearable Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: March 16, 2026
Received: March 17, 2026

Dear Dale WANG:

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)*
K260864

Device Name
Mother's Nature W1 Warming Wearable Breast Pump

Indications for Use *(Describe)*
The Mother's Nature W1 Warming Wearable Breast Pump (Model W1) is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It 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 – K260864

1. Submitter	**Company:** Shenzhen TPH Technology Co., Ltd. **Address:** Room 203, 2nd floor, 29th Building, Lianchuang Technology Park, No.21 Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, China 518000 **Tel.:** 86-19129492601
Contact Person	**Name:** Dale WANG **Position Title:** Regulatory Affairs Engineer **Company:** Shenzhen TPH Technology Co., Ltd. **Tel.:** 86-19129492601 **Email:** dale@tph-tech.com
Date Prepared	June 1, 2026
2. Device Information	**Device Name:** Mother's Nature W1 Warming Wearable Breast Pump **Device Model:** W1 **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 **Manufacturer:** Shenzhen TPH Technology Co., Ltd.
3. Predicate Device Information	**Predicate Device Name:** Wearable Breast Pump (Model W6) **Model:** W6 **510(k) Number:** K250383 The predicate device has not been subject to a design-related recall.
4. Device Description	The Mother's Nature W1 Warming Wearable Breast Pump (Model W1) is powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user. The Mother's Nature W1 Warming Wearable Breast Pump is breast pump powered by lithium battery, utilizing an embedded control program to manage all device functions. The main components of these pumps include: Pump motor, Valve, Control board, and Milk collector. The user interface allows the user to switch from Stimulation, Expression, Hybrid and Auto modes and control the vacuum levels within those modes. All available modes consist of 12 suction levels. The Mother's Nature W1 Warming Wearable

Breast Pump is capable of providing vacuum levels from 40-150 mmHg with cycling rates from 72-133 cycles per minute in Stimulation mode, vacuum levels from 80-245 mmHg with cycling rates from 16-103 cycles per minute in Expression mode, vacuum levels from 40-245 mmHg with cycling rates from 32-113 cycles per minute in Hybrid mode, and vacuum levels from 40-245 mmHg with cycling rates from 31-133 cycles per minute in Auto mode. The motor unit operates on embedded software. Software updates by end-users are not supported. The subject devices are for repeated use by a single user in a home environment. The device is provided non-sterile.

The Mother's Nature W1 Warming Wearable Breast Pump is powered by an internal rechargeable lithium-ion polymer battery and charged with a 5 V DC USB adaptor (not included with the device). The motor unit does not function when charging.

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 collector, which can be used for storage. To prevent milk from flowing into the vacuum system, a back flow protection membrane physically separates the milk-contacting pathway from the vacuum system.

All other components (i.e., motor unit/housing) of the subject devices are not in contact with the breast. All milk contacting components are compliant with 21 CFR 174-179.

5. Indications for Use

The Mother's Nature W1 Warming Wearable Breast Pump (Model W1) is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.

6. Comparison of Intended Use and Technological Characteristics of the Subject Device and Predicate Device

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

Table 1. Comparison between Subject Device and Predicate Device

Item	**Subject Device** Mother's Nature W1 Warming Wearable Breast Pump (Model W1)	**Predicate Device** Wearable Breast Pump (Model W6) **K250383**	**Comment**
Device Classification Name	Pump, Breast, Powered	Pump, Breast, Powered	Same
Classification	Class II	Class II	Same
Regulation No.	21 CFR 884.5160	21 CFR 884.5160	Same
Product Code	HGX	HGX	Same
Patient Population	Lactating women	Lactating women	Same
Indications for Use	The Mother's Nature W1 Warming Wearable Breast Pump(Model W1) is a powered	The Wearable Breast Pump (Model W6) is a powered breast pump intended to be	Same

	breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.	used by lactating women to express and collect milk from their breasts. It is intended for a single user.	
Pump Options	Single	Single	Same
Cycling Control Mechanism	Micro controller	Micro controller	Same
Backflow Protection	YES	YES	Same
Suction Modes	Stimulation mode Expression mode Hybrid mode Auto mode	Stimulation mode Expression mode Massage mode Auto mode	Different
Suction Levels	12	12	Same
Single User	Yes	Yes	Same
Hot Compress Function	Yes	Yes	Same
Vacuum Range (Stimulation mode)	40-150 mmHg	40-120 mmHg	Different
Vacuum Range (Expression mode)	80-245 mmHg	105-245 mmHg	Different
Vacuum Range (Massage mode)	None	40-150 mmHg	Different
Vacuum Range (Hybrid mode)	40-245 mmHg	None	Different
Vacuum Range (Auto mode)	40-245 mmHg	40-245 mmHg	Same
Cycle Speed (Stimulation mode)	72-133 cycles/minute	90-143 cycles/minute	Different
Cycle Speed (Expression mode)	16-103 cycles/minute	30-105 cycles/minute	Different
Cycle Speed (Massage mode)	None	87-128 cycles/minute	Different
Cycle Speed (Hybrid mode)	32-113 cycles/minute	None	Different
Cycle Speed (Auto mode)	31-133 cycles/minute	30-143 cycles/minute	Different
Controls	On-Off switch/pause, Vacuum adjustment,	On-Off switch/mode change, Vacuum adjustment,	Similar

	Mode change/Hot compress switch button, Night light button	Hot compress switch button/pause	
Power Supply	Li-ion battery	Li-ion battery	Same
Indicators	Yes, LED	Yes, LED	Similar
Design	Wearable pump with combined Milk collector and Flange	Wearable pump with combined Milk collector and Flange	Same

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 wearable operation, power supply, and user interface. However, as shown in the table above, there are technological differences between the subject and predicate devices, including different overall vacuum/cycle specifications and available modes. The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness and can be evaluated through performance testing.

7. Summary of Non-Clinical Performance Testing

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

Biocompatibility Testing

Biocompatibility testing 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*." The biological evaluation included the following testing conducted on the finished device:

- **Cytotoxicity** – evaluated in accordance with ISO 10993-5:2009
- **Sensitization** – evaluated in accordance with ISO 10993-10:2021
- **Irritation** – evaluated in accordance with ISO 10993-23:2021

The results of these studies demonstrated that the device is non-cytotoxic, non-sensitizing, and non-irritating, supporting the biological safety of the device for its intended use.

Electrical Safety

Electrical Safety Testing was conducted in accordance with following standards:

- IEC 60601- 1 Edition 3.2 2020-08 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 Edition 3.1 2020-07 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.

The results of this testing demonstrate that the device meets applicable requirements for electrical safety, battery safety, and suitability for use in the home healthcare environment, with no evidence of unacceptable risk or degradation in performance under the tested conditions.

Electromagnetic Compatibility

Electromagnetic Compatibility Testing was conducted in accordance with IEC 60601-1-2:2014+A1:

2020 Medical Electrical Equipment - Part 1-2: "*General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests*." The results demonstrate that the device complies with applicable emissions and immunity requirements, and that essential performance is maintained without unacceptable degradation during exposure to electromagnetic disturbances.

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.*" The software documentation included the software description, hazard analysis, verification and validation testing, and revision history, consistent with expectations for a Basic Documentation level device. The results of software verification and validation demonstrate that the software performs as intended, with no unresolved anomalies that would impact device safety or effectiveness.

Performance and Use Life Verification

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/level demonstrated that the devices meet vacuum pressure/cycle frequency specifications.
- Backflow protection testing was conducted to verify liquid does not backflow into the motor unit.
- Use life testing was conducted to demonstrate that the devices maintain their specifications throughout their proposed use life.
- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated use-life.
- Hot Compress temperature testing was conducted to demonstrate that the Hot Compress function remains functional during stated use-life.

The results of these tests demonstrate that the device meets its performance specifications, maintains functional integrity over its intended use life, and performs as intended without evidence of degradation that would impact safety or effectiveness.

8. Substantial Equivalence Conclusion:

The results of the performance testing described above demonstrate that Mother's Nature W1 Warming Wearable Breast Pump (Model W1) is as safe and effective as the predicate device and support a determination of substantial equivalence.