February 13, 2026

Shenzhen TPH Technology Co., Ltd.
Dale Wang
Regulatory Affairs Engineer
Room 203, 2nd floor, 29th Building, Lianchuang Technology
Pa Rk, #21 Bulan Road, Xialilang Community, NanwanStreet, Lon,
Shenzhen, 518100
CHINA

Re: K252420
Trade/Device Name: Wearable Breast Pump (Model W12)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: January 15, 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: 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, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252420

Device Name
Wearable Breast Pump (Model W12)

Indications for Use *(Describe)*
The Wearable Breast Pump (Model W12) 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.

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510(k) Summary – K252420

1. Submitter Information

Applicant: Shenzhen TPH Technology Co., Ltd.
Address: Room 203, 2nd floor, 29th Building, Lianchuang Technology Park, No.21 Bulan Road, Xialilang, Shenzhen, Guangdong 518100 CHN
Tel.: 8619129492601

2. Correspondent Information

Contact: Dale Wang
Regulatory Affairs Engineer
Shenzhen TPH Technology Co., Ltd.
Email: dale@tph-tech.com

3. Date prepared: February 10, 2026

4. Device Information

Device Name:	Wearable Breast Pump (Model W12)
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:	Wearable Breast Pump (Model W8)
510(k) Number:	K242850
Manufacturer:	Shenzhen TPH Technology Co., Ltd.

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

6. Device Description

The Wearable Breast Pump (Model W12) 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. The Wearable Breast Pump (Model W12) is a breast pump powered by lithium battery, utilizing an embedded control program to manage all device functions. The main components of these pumps include: pump, valve, control board, and milk collector. The user interface allows the user to switch from stimulation, expression, auto, and massage modes and control the vacuum levels within those modes. The Wearable Breast Pump (Model W12) also includes a 'Hot Compress' mode not associated with any vacuum pressure or cycle speed. When enabled, the flange is heated, the symbol indicating heating will light up, and the maximum temperature is ≤ 42°C.

All available modes consist of 12 vacuum levels. The Wearable Breast Pump (Model W12) is capable of providing vacuum levels from 40-150 mmHg with cycling rates from 86-127 cycles per minute in stimulation mode, vacuum levels from 120-245 mmHg with cycling rates from 34-109 cycles per minute in expression mode, vacuum levels from 40-245 mmHg with cycling rates from 34-130 cycles per minute in auto mode, and vacuum levels from 40-120 mmHg with cycling rates from 90-143 cycles per minute in massage mode. The Wearable Breast Pump (Model W12) is charged with a 5 V DC adaptor and powered by an internal

rechargeable lithium-ion polymer battery. The motor unit operates on embedded software. Software updates by end-users are not supported. The subject device is for repeated use by a single user in a home environment. The device is provided non-sterile.

The motor unit operates on a rechargeable battery and does not function when charging. The rechargeable battery can be charged from the external USB adapter if the motor unit is not in operation.

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.

All other components (i.e., motor unit/housing) of the subject device is not in contact with the breast. All milk contacting components are compliant with 21 CFR 177.

7. Indications for Use

The Wearable Breast Pump (Model W12) 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.

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

	Wearable Breast Pump (Model W12) K252420 Subject Device	**Wearable Breast Pump (Model W8) K242850 Predicate Device**	**Comparison**
Product Name	Wearable Breast Pump (W12)	Wearable Breast Pump (Model W8)	**N/A**
Product Code	HGX	HGX	**Same**
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	**Same**
Regulatory Class	Class II	Class II	**Same**
Patient Population	Lactating Women	Lactating Women	**Same**
Indications for Use	The Wearable Breast Pump (Model W12) 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.	The Wearable Breast Pump（Model W8） 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.	**Same**
Pump Options	Single	Single	**Same**
Cycling control mechanism	Microcontroller	Microcontroller	**Same**
Backflow Protection	Yes	Yes	**Same**
Suction Modes	Stimulation Mode, Expression Mode, Auto Mode, Massage Mode, Hot Compress Mode	Stimulation Mode, Expression Mode, Auto Mode, Massage Mode	**Different**

Suction levels	12	15	**Different**
Adjustable suction levels	Yes	Yes	**Same**
Suction strength (Stimulation)	40-150 mmHg	40-170 mmHg	**Different**
Suction strength (Expression)	120-245 mmHg	120-245 mmHg	**Same**
Suction strength (Massage)	40-120 mmHg	40-140 mmHg	**Different**
Suction strength (Auto)	40-245 mmHg	40-245 mmHg	**Same**
Cycles per minute (Stimulation)	86 to 127 cpm	77 to 127 cpm	**Different**
Cycles per minute (Expression)	34 to 109 cpm	32 to 92 cpm	**Different**
Cycles per minute (Massage)	90 to 143 cpm	79 to 143 cpm	**Different**
Cycles per minute (Auto)	34 to 130 cpm	32 to 136 cpm	**Different**
Controls	On-Off switch, mode selection/long press, vacuum adjustment, LED display, heat compress button	On-Off switch, mode selection/long press, vacuum adjustment, LED display	**Similar**
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**
Heating element	Yes, ≤42°C	No	**Different**
Mobile application	No	No	**Same**
Materials	Milk collector/linker: polypropylene Flange/valve/diaphragm: Silicone Pump motor/housing: ABS	Milk collector/linker: polypropylene Flange/valve/diaphragm: Silicone Pump motor/housing: ABS	**Same**

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 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, inclusion of a heating element, and available modes (hot compress mode added to subject device). 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 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."* The following tests were conducted on the predicate device:

- Cytotoxicity (ISO 10993-5:2009)
- Skin Sensitization (ISO 10993-10:2010)
- Skin Irritation (ISO 10993-10:2010)

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

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 60601-1-2:2020 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."*

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 into the tubing.
- Heating element performance to ensure temperature was within specification.
- Use life testing was conducted to demonstrate that the device maintains its specifications throughout its 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 battery life.

10. Conclusion

The results of the performance testing described above demonstrate that the Wearable Breast Pump (Model W12) is as safe and effective as the predicate device and support a determination of substantial equivalence.