February 21, 2025

Shenzhen TPH Technology Co., Ltd.
Peter Chen
General Manager
Room 203, 2nd floor,29th Building,Lianchuang Technology Park
No.21 Bulan Rd, Xialilang Cmty, Nanwan St, Longgang Dist
Shenzhen, Guangdong 518100
CHINA

Re: K242850
Trade/Device Name: Wearable Breast Pump (model W8)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: January 23, 2025

Dear Peter Chen:

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,
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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)*
K242850

Device Name
Wearable Breast Pump (Model W8)

Indications for Use *(Describe)*
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.

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 – K242850

1. Submitter:

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Contact Person:

Peter Chen

General Manager

Shenzhen TPH Technology Co., Ltd.

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Date Prepared: February 21, 2025

2. Device Information:

Device Name: Wearable Breast Pump（Model W8）

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

3. Predicate Device Information

Wearable Breast Pump, model S12 cleared under **K212180**.

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

4. Device Description:

The Wearable Breast Pump（Model W8）is a wearable powered breast pump designed for lactating woman to express and collect milk from the breast.

There are 4 modes available for the device which are Expression mode, Massage mode, Auto mode and Stimulation mode. There is a LED status display for W8, including working mode, and battery indicator can be shown on the pump body. The user interface includes on/off switch, mode selection/long press, and vacuum adjustment.

W8 operated as a single or double pumping system, one on each breast. The pump is provided non-sterile and reusable by a single user. The device is powered by rechargeable Li-ion battery (3.7V, 1200mAh). W8 is designed not to be used during charging.

The breast pump does not incorporate any off-the-shelf (OTS) software. The device incorporates embedded software which controls all the features of the product. All milk contacting components of the device are compliant with 21 CFR 177 which is applicable for the subject device.

5. Indications for Use:

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.

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 to Predicate Device

Item	**Proposed Device** Wearable Breast Pump (Model W8)	**Proposed Device** Wearable Breast Pump, model S12 (**K212180)**	**Comment**
Classification	Pump, Breast, Powered	Pump, Breast, Powered	Same
Regulation	Class II, 21 CFR 884.5160	Class II, 21 CFR 884.5160	Same
Product code	HGX	HGX	Same
Indications for Use	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.	The Wearable Breast Pump, model S12 is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.	Similar
Patient Population	Lactating women	Lactating women	Same
Anatomical Sites	Breast	Breast	Same
Single user	YES	YES	Same
Single/double pump	Single	Single	Same
Media separation (backflow protection)	YES	YES	Same
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor	Same
Specifications			
Power Supply	Li-ion battery	Li-ion battery	Same
Suction Strength (Stimulation)	40-170 mmHg	35-110 mmHg	Different
Cycle Speed: Stimulation	77 to 127 cycles/minute	70 to 114 cycles/minute	Different
Suction Strength (Expression)	120-245 mmHg	35~245 mmHg	Different
Cycle Speed: Expression	32 to 92 cycles/minute	23 to 90 cycles/minute	Different
Suction Strength (Massage)	40-140 mmHg	none	Different
Cycle Speed: Massage	79-143 cycles/minute	none	Different
Suction Strength (Auto)	40-245mmHg	none	Different
Cycle Speed: Auto	32-136 cycles/minute	none	Different
Suction levels	15	9	Different
User interface (LED display)			

User control	On-Off switch, mode selection/long press, vacuum adjustment	On-Off switch, mode selection, vacuum adjustment	Different
Adjustable suction levels	YES	YES	Same
Wireless technology	No	No	Same
Component design	Milk collector and flange	Milk collector and flange	Same
Milk collector Capacity	180 ml	180ml	Same
Flange size	24mm and 27mm	24mm and 27mm	Same
Material			
Milk collector/Linker	Polypropylene	Polypropylene	Same
Flange/Valve/Diaphragm	Silicone	Silicone	Same
Pump motor/outer housing	ABS	ABS	Same

In comparison to the predicate device, the subject device has the same intended use and similar indications for use – the expression and collection of breast milk.

As seen in the comparison table, the subject and predicate devices have different technological features, including the user interface, vacuum range, cycle speed range, suction levels. These technological differences do not raise different questions of safety and effectiveness.

7. Summary of Non-Clinical Performance Testing:

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

Performance and Use Life Verification

Bench performance testing was conducted to evaluate device performance:
-Vacuum pressure
-Cycle speed
-Backflow protection
-Battery capacity & service time
-Charging time

Device specifications were met for all tests conducted.

Biocompatibility testing

The biocompatibility evaluation for the Wearable Breast Pump 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:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2021)
- Irritation (ISO 10993-10:2021)

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

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Wearable Breast Pump device, consisting of all the modules and accessories in the system. The system complies with the following standards:
- IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance.

- 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,
- IEC 60601-1-2 :2014/A1:2021 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests standard for EMC.
- IEC 62133-2 :2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Software Verification and Validation Testing
Software verification and validation was conducted as recommended in the 2023 FDA guidance document, “Content of Premarket Submissions for Device Software Functions.” with a Basic Documentation Level.

8. Substantial Equivalence Conclusion:

The results of the performance testing described above demonstrate that the Wearable Breast Pump (Model W8) is as safe and effective as the predicate device and supports a determination of substantial equivalence.