September 8, 2025

Shenzhen TPH Technology Co., Ltd.
Dale Wang
Regulatory Affairs Engineer
Room 203, 2nd floor,29th Building,Lianchuang Technology Park
No.21 Bulan Rd, Xialilang Cmty, Nanwan St, Longgang Dist
Shenzhen, Guangdong 518100
CHINA

Re: K251754
Trade/Device Name: Wearable Breast Pump (Model S33)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: Class II
Product Code: HGX
Dated: March 12, 2025
Received: June 9, 2025

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 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

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)*
K251754

Device Name
Wearable Breast Pump (Model S33)

Indications for Use *(Describe)*
The Wearable Breast Pump (Model S33) 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

# K251754

| | |
|---|---|
| **1. Submitter** | Shenzhen TPH Technology Co., Ltd.<br>Room 203, 2nd floor, 29th Building, Lianchuang Technology Park No.21 Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, China.<br>Tel.: +86-755-82703212 |
| Contact Person | Peter Chen<br>General Manager<br>Shenzhen TPH Technology Co., Ltd.<br>peter@tph-tech.com |
| Date Prepared | September 4, 2025 |
| **2. Device Information** | **Device Name:** Wearable Breast Pump（Model S33）<br>**Common Name:** Powered breast pump<br>**Regulation Number:** 21 CFR 884.5160<br>**Regulation Name:** Powered breast pump<br>**Product Code:** HGX (Pump, Breast, Powered)<br>**Classification Panel:** Obstetrics/Gynecology<br>**Regulatory Class:** Class II |
| **3. Predicate Device Information** | Wearable Breast Pump, model W8 cleared under **K242850**.<br>The predicate device has not been subject to a design-related recall. |

## 4. Device Description

The Wearable Breast Pump（Model S33）is a wearable powered breast pump designed for lactating woman to express and collect milk from the breast.

It is an electrically powered, software-controlled, digital pump. It is powered by a rechargeable lithium ion battery (3.7 V, 1000mAh) that can be charged using the USB cable provided with the device. The device is designed not to be used during charging. The device utilizes an embedded control program to manage all product functions and does not incorporate any off-the-shelf (OTS) software. The main components of this pump include pump motor, valve, flange, silicone diaphragm, USB charging cable, bra extension strap and milk collector. The pump is provided non-sterile and reusable by a single user in home environment.

There are four (4) operating modes available for the device – Stimulation mode, Expression mode, Massage mode, and Auto mode. The device includes nine (9) suction levels within each mode. Wearable Breast Pump (Model S33) is capable of providing vacuum levels from 40-160 mmHg with cycling rates from 91 -121 cycles per minute in Stimulation mode, vacuum levels from 120-245 mmHg with cycling

rates from 27-88 cycles per minute in Expression mode, vacuum levels from 40-120 mmHg with cycling rates from 92-130 cycles per minute in Massage mode and vacuum levels from 40-245 mmHg with cycling rates from 27-121 cycles per minute in auto mode. The device is equipped with an LED status display that displays information regarding working mode, operating time, and battery status. The user interface includes on/off switch that also acts as mode selection switch (through long press), pause button and vacuum level adjustment buttons.

Wearable breast pump (Model S33) is designed to be used as a single pumping system that can be converted to double pumping by using two devices, one on each breast. To prevent milk from flowing into the vacuum system, the device uses a silicone diaphragm that physically separates the milk contacting pathway from the vacuum system. All milk contacting components of the device are compliant with 21 CFR 177.

## 5. Indications for Use

The Wearable Breast Pump（Model S33）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**<br>Wearable Breast Pump (Model S33) | **Proposed Device**<br>Wearable Breast Pump, (Model W8) (**K242850)** | **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 S33) is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user. | The Wearable Breast Pump (Model W8) is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user. | Same |
| Patient Population | Lactating women | Lactating women | Same |
| Single user | Yes | Yes | Same |
| Single/double pump | Single | Single | Same |
| Media separation (backflow protection) | Yes | Yes | Same |
| Control Mechanism | Microprocessor | Microprocessor | Same |
| Power Supply | 3.7V 1000mAh Li-ion battery | 3.7V 1200mAh Li-ion battery | Similar |
| **Suction Strength (mmHg)** | **Stimulation: 40 – 160**<br>**Expression: 120 - 245**<br>**Massage: 40- 120**<br>**Auto: 40 - 245** | **Stimulation: 40 - 170**<br>**Expression: 120 - 245**<br>**Massage: 40- 140**<br>**Auto: 40 - 245** | **Different** |
| **Cycle Speed (cycles per minute)** | **Stimulation: 91 – 121**<br>**Expression: 27 - 88**<br>**Massage: 92 - 130**<br>**Auto: 27 - 121** | **Stimulation: 77 - 127**<br>**Expression: 32 - 92**<br>**Massage: 79 - 143**<br>**Auto: 32 - 136** | **Different** |
| **Suction levels** | **9** | **15** | **Different** |
| User control | On-off/mode selection switch, vacuum adjustment buttons, pause button, LED display | On-off/mode selection switch, vacuum adjustment buttons, pause button, LED display | Same |

| | | | |
|---|---|---|---|
| Device Design | Diaphragm pump | Diaphragm pump | Same |

The indications for use of the subject and predicate devices are similar, and both devices have the same intended use (i.e., for the 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 devices, as compared to the predicate device, do not raise different questions of safety and effectiveness.

## 7. Summary of Non-Clinical Performance Testing:

**Biocompatibility testing**

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."

**Electrical safety and Electromagnetic Compatibility (EMC)**

Electrical safety and EMC testing were conducted on the Wearable Breast Pump (Model S33), 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.

**Performance and Use Life Verification**

Bench performance testing was conducted to demonstrate that the subject device meets its design requirements and performs as intended:

- 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.
- Use life testing was conducted to demonstrate that the devices maintain their 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

## 8. Substantial Equivalence Conclusion:

The results of the performance testing described above demonstrate that the Wearable Breast Pump (Model S33) is as safe and effective as the predicate device and supports a determination of substantial equivalence.