April 21, 2025

Shenzhen TPH Technology Co., Ltd.
Peter Chen
General Manager
Room 203, 2nd floor, 29th Building, Lianchuang Technology
Park, No.21 Bulan Road, Xialilang Community, Nanwan Street,
Shenzhen, Guangdong 518100
CHINA

Re: K243508
Trade/Device Name: Wearable breast pump (Model S12A)
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, PhD
Assistant Director
DHT3B: Division of Reproductive,
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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)*
K243508

Device Name
Wearable Breast Pump (Model S12A)

Indications for Use *(Describe)*
The Wearable Breast Pump (Model S12A) 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

# K243508

**Prepared in accordance with the requirements of 21 CFR Part 807.92**

| | |
|---|---|
| **1. Submitter:** | Shenzhen TPH Technology Co., Ltd.<br>Room 203,2nd floor,29th Building, Lienchiang Technology Park, No. 21 Bulan Road, Vialling Community, Nandan Street, Longgang District, Shenzhen, China.<br>Tel.: +86-13302476262<br>Contact Person: Peter Chen<br>Emai: peter@tph-tech.com |
| **Date Prepared:** | April 21, 2025 |
| **2. Device Information:** | **Device Name:** Wearable Breast Pump (Model S12A)<br>**Common Name:** Powered Breast Pump<br>**Regulation Number:** 21 CFR 884.5160<br>**Regulation Name:** Powered Breast Pump<br>**Product code:** HGX<br>**Regulatory Class:** Class II |
| **4. Predicate Device Information:** | **Device Name:** Lucy Breast Pump<br>**510(k) Number**: K213311<br>**Manufacturer**: Willow Innovations, Inc.<br>The predicate device has not been subject to a design-related recall. |

## 5. Device Description

The Wearable Breast Pump (Model S12A) is an electrically powered, software-controlled, single user pump designed for lactating women to express and collect milk from the breast.

The device has three modes of operation - Expression mode, Stimulation mode, and Auto mode, with multiple suction levels for each mode. Stimulation mode consists of pressures ranging from 30/160-120/160 mmHg and cycle speeds of 74-134 cycles/min, expression mode consists of pressure ranges from 120-245 mmHg and cycle speeds of 29-92 cycles/min, and auto mode consists of pressure ranges from 30-245 mmHg and cycle speeds of 29-128 cycles per minute. There is an LED status display for S12A, and the working mode and battery indicator are shown on the pump body.

S12A may be operated as a single or double pumping system. For a user to pump both breasts simultaneously, they would need to use two S12A devices at the same time, one on each breast. The pump is provided non-sterile and can be re-used by a single user. The device is powered by a Li-ion battery and charged using a 5V DC adaptor. The device is designed not to be used during charging.

The breast pump does not incorporate any off-the-shelf (OTS) software, and it incorporates embedded software which controls all the features of the product. All milk contacting components of the device are

compliant with 21 CFR 177.

## 6. Indications for Use

The Wearable Breast Pump (Model S12A) 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.

## 7. Predicate Device Comparison

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

**Table 1 Specific Comparison to Predicate Device**

| Item | Subject Device<br>Wearable Breast Pump (Model S12A)<br>（K243508） | Predicate Device<br>Lucy Breast Pump<br>(K213311) | Comparison |
|---|---|---|---|
| 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 S12A) 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 Lucy Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Lucy Breast Pump is intended for a single user. | Same |
| Single-User | Yes | Yes | Same |
| Single/double pump | Single or Double | Single or Double | Same |
| User Interface | On-Off switch, mode selection, vacuum adjustment, LED display | On-Off switch, mode selection,, vacuum adjustment, LED light | **Different** |
| Materials | Milk collector/Linker: Polypropylene<br>Flange/Valve/Diaphragm: Silicone | Flange: Polypropylene | **Different** |
| Power Source | Internal non-replaceable rechargeable Li-ion battery, charged with AC Power Adapter | Internal non-replaceable rechargeable Li-ion battery, charged with AC Power Adapter | Same |
| Control Mechanism | Microprocessor | Microprocessor | Same |
| **Specifications** | | | |
| Maximum Vacuum | -250 mmHg | -295 mmHg | **Different** |
| Vacuum Range (mmHg) | Stimulation: -30 to -160 mmHg<br>Expression: -120 to -245 mmHg<br>Auto: -30 to -245mmHg | -75 to -280mmHg | **Different** |
| Cycle Speed Range (cycles/minute) | Stimulation:74 - 134 cycles/minute<br>Expression: 29 - 92 cycles/minute<br>Auto:29 - 128 cycles/minute | 30 - 100 cycles/minute | **Different** |
| Backflow/Overflow Protection | Yes - Diaphragm prevents overflow of milk into the pumping mechanism. | Yes - Diaphragm prevents overflow of milk into the pumping mechanism. | Same |

The indications for use of the subject and predicate devices are identical; therefore, they 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 control mechanism,

backflow protection, and power source. However, as shown in the table above, there are technological differences between the subject and predicate devices, including different vacuum and cycle specifications, user interface, and device materials. These differences in technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

## 8. Performance Testing:

### Biocompatibility testing

The biocompatibility evaluation, including cytotoxicity, skin irritation, and skin sensitization, for the subject device 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)
- Skin Sensitization (ISO 10993-10:2021)
- Skin Irritation (ISO 10993-23:2021

The patient-contacting components were shown to be non-cytotoxic, non-irritating, and non-sensitizing.
All milk contacting components of the device are compliant with 21 CFR 177.

### Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device in accordance with the following standards:

- IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, *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, *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, was evaluated at basic documentation level in accordance with 2023 FDA Guidance: *Content of Premarket Submissions for Device Software Functions* .

### 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/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 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 -Vacuum test.

## 9. Substantial Equivalence Conclusion:

The results of the performance testing described above demonstrate that the Wearable Breast Pump (Model S12A) is as safe and effective as the predicate device and supports a determination of substantial equivalence.