May 21, 2026

Shenzhen TPH Technology Co., Ltd.
Dale Wang
Regulatory Affairs Engineer
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Bulan Rd., Xialilang Community, Nanwan St., Longgang District
Shenzhen, 518000
CHINA

Re: K254244
Trade/Device Name: Wearable Breast Pump (Model S39)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: April 21, 2026
Received: April 21, 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, the 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 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,

Monica D. Garcia -S

Monica D. Garcia, PhD
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
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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)*
K254244

Device Name
Wearable Breast Pump (Model S39)

Indications for Use *(Describe)*
The Wearable Breast Pump (Model S39) 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.

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510(k) Summary – K254244

1. Submitter

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Tel.: 86-19129492601

Email: dale@tph-tech.com

Date Prepared

May 21, 2026

2. Device Information

Device Name: Wearable Breast Pump (Model S39)

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

Predicate Device Name: Wearable Breast Pump (Model W8)

510(k) Number: K242850

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

4. Device Description

The Wearable Breast Pump (Model S39) is a wearable, software controlled, powered breast pump intended to be used by lactating women to express and collect milk from their breast. The pump is provided non-sterile and can be re-used by a single user. The device is electrically powered through a rechargeable Lithium battery (3.7V, 1200mAh) that can be charged using the USB cable provided with the device with a qualified 5V DC Adaptor (not included with the device). The device is designed not to be used during charging.

The device includes four modes of operation, i.e., Stimulation mode, Expression mode, Massage mode, and Auto mode with 12 suction levels within each mode. The device includes an LED screen display that displays information regarding device operation including current working mode, suction level, use-time and battery indicator. The device user interface also includes power on/off/mode switch and suction level increase and decrease buttons. The subject device includes a diaphragm to prevent milk backflow into the vacuum system .

The Wearable Breast Pump (Model S39)can be operated as a single or double pumping system, where a user would need to use two Model S39 devices at the same time, one on each breast to allow for double pumping..

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.

5. Indications for Use

The Wearable Breast Pump (Model S39) 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. Comparator Table for the Subject and Predicate Devices

Item	**Subject Device** Wearable Breast Pump (Model S39)	**Predicate Device** 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 S39) 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
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
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor	Same
Power Supply	Li-ion battery	Li-ion battery	Same
Suction Modes	Four (Stimulation, Expression, Massage and Auto)	Four (Stimulation, Expression, Massage and Auto)	Same
Suction Strength	Stimulation mode: 40 to 150 Expression mode: 105 to 245 Massage mode: 40 to 120 Automatic mode: 40 to 245	Stimulation mode: 40 to 170 Expression mode: 120 to 245 Massage mode: 40 to 140 Automatic mode: 40 to 245	**Different**

Cycle Speed	Stimulation mode: 77 to 107 Expression mode: 35 to 98 Massage mode: 79 to 118 Automatic mode: 35 to 113	Stimulation mode: 77 to 127 Expression mode: 32 to 92 Massage mode: 79 to 143 Automatic mode: 32 to 136	**Different**
Suction Levels	12 levels for all modes	15 levels for all modes	**Different**
User Control	On-Off switch, mode and vacuum level adjustment	On-Off switch, mode and vacuum level adjustment	Same
Material	Polypropylene, Silicone, ABS	Polypropylene, Silicone, ABS	Same

The subject and predicate devices have similar indications for use statements and the same intended use, i.e, the expression and collection of breast milk from the breasts of lactating women.

As seen in the comparison table, the subject and predicate devices have different technological features, including vacuum range, cycle speed range, and suction levels. These technological differences 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

The biocompatibility evaluation for the patient contacting components of 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," including the following tests:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2021)
- Irritation (ISO 10993-23:2021)

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. 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" consistent with a basic documentation level.

Performance and Use Life Verification

Bench performance testing was conducted to evaluate device performance, including:

- Vacuum pressure and cycle speed verification for all modes and levels of operation
- Backflow protection testing
- Battery charging time, capacity and service time testing
- Use life testing

Device specifications were met for all tests conducted.

8. Substantial Equivalence Conclusion:

The results of the performance testing described above demonstrate that the Wearable Breast Pump (Model S39) is as safe and effective as the predicate device and supports a determination of substantial equivalence.