



July 1, 2024

Shenzhen TPH Technology Co., Ltd.
Peter Chen
General Manager
Room 203, 2nd floor, 29th Building, Lianchuang Technology
Park, Nanwan, Longgang District
Shenzhen, Guangdong 518100
CHINA

Re: K240536
Trade/Device Name: Wearable Breast Pump (Model S32)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: May 29, 2024

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.

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

Indications for Use

510(k) Number (if known)

K240536

Device Name

Wearable Breast Pump (Model S32)

Indications for Use (Describe)

The Wearable Breast Pump (Model S32) is intended to express milk from lactating women in order to collect milk from their breasts. The device 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.

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510(k) Summary – K240536

1. Submitter Information

Applicant: Shenzhen TPH Technology Co., Ltd.
Address: 5th Floor, Building No.29 East side,
Lianchuang 2th technology park, Bulan
Road, Nanwan Community, Longgang
District, Shenzhen, China

2. Correspondent Information

Contact: Peter Chen
General Manager
Phone: + 86 (755) 827-03212
Email: peter@tph-tech.com

3. Date prepared: June 24, 2024

4. Device Information

Device Name:	Wearable Breast Pump (Model S32)
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 S12)
510(k) Number:	K212180
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 S32), is an electrically powered wearable single breast pump consisting of the following key components: a flange, pump motor, silicone diaphragm, milk collector, bra adjustment buckle, valve, and USB charging cable. It is designed to work in the user's bra and has a rechargeable battery so it can be used hands-free without any external power cords. The motor unit includes a press-button user interface, pump body, and LED display. Pumping can be performed on one breast (single pumping). The user interface allows the user to switch from stimulation, expression, massage, and auto modes and control the vacuum levels within those modes.

All available modes consist of 9 vacuum levels. The S32 model is capable of providing vacuum levels from 40-120 mmHg with cycling rates from 86-110 cycles per minute in stimulation mode, vacuum levels from 120-245 mmHg with cycling rates from 33-109 cycles per minute in expression mode, vacuum levels from 40-120 mmHg with cycling rates from 90-120 cycles per minute in massage mode, and vacuum levels from 40-245 mmHg with cycling rates from 33-120 cycles per minute in auto mode. The model S32 Wearable Breast Pump 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 not 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 are not in contact with the breast. All milk contacting components are compliant with 21 CFR 174-179.

7. Indications for Use

The Wearable Breast Pump (Model S32) is intended to express milk from lactating women in order to collect milk from their breasts. The device 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 S32) K240536 Subject Device	Wearable Breast Pump (Model S12) K212180 Predicate Device	Comparison
Product Name	Wearable Breast Pump (Model S32)	Wearable Breast Pump (Model S12)	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 S32) 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 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.	Same
Pump Options	Single	Single	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Backflow Protection	Yes	Yes	Same
Suction Modes	Stimulation Mode and Expression Mode	Stimulation Mode and Expression Mode	Same
Suction levels	9	9	Same
Adjustable suction levels	Yes	Yes	Same

Vacuum range: Stimulation	-40 to -120 (± 5) mmHg	-40 to -105 (± 5) mmHg	Different
Vacuum range: Expression	-120 to -245 (± 5) mmHg	-40 to -245 (± 5) mmHg	Different
Vacuum range: Massage	-40 to -120 (± 5) mmHg	N/A	Different
Vacuum range: Auto	-40 to -245 (± 5) mmHg	N/A	Different
Cycle Speed: Stimulation	86 to 110 (± 2) cycles/minute	70 to 114 cycles/minute	Different
Cycle Speed: Expression	33 to 109 (± 2) cycles/minute	23 to 90 cycles/minute	Different
Cycle Speed: Massage	90 to 120 (± 2) cycles/minute	N/A	Different
Cycle Speed: Auto	33 to 120 (± 2) cycles/minute	N/A	Different
Controls	On-Off switch, vacuum adjustment, mode change/power	On/Off button; Mode selection Increase/decrease vacuum button;	Similar
Power Supply	Li-Ion Battery	Li-Ion Battery	Same
Indicators	Yes, LED	Yes, LED	Similar
Materials	Milk Container: Polypropylene Flange: Silicone Pump Outer Housing: Acrylonitrile Butadiene Styrene (ABS) plastic	Milk Container: Polypropylene Flange: Silicone Pump Outer Housing: Acrylonitrile Butadiene Styrene (ABS) plastic	Same

The indications for use of the subject and predicate device are identical, and 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 wearable operation, power supply, and user interface. However, as shown in the table above, there are technological differences between the subject and predicate device, including different overall vacuum/cycle specifications and available modes. The different technological characteristics of the subject device, 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 provided in accordance with Attachment G of 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

Testing was conducted in accordance with 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 IEC 60601-1-2:2014 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.
- 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 subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.