February 11, 2022

Shenzhen TPH Technology Co., Ltd.
Peter Chen
General Manager
Bulan Road, Nanwan Community, Longgang District
Shenzhen, Guangdong 518100
China

Re: K212180
Trade/Device Name: Wearable Breast Pump (Model S12)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: January 10, 2022
Received: January 14, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for
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)*
K212180

Device Name
Wearable Breast Pump (Model S12)

Indications for Use *(Describe)*
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.

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 – K212180

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
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2. Correspondent Information

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

3. Date prepared: February 10, 2022

4. Device Information

Device Name:	Wearable Breast Pump (Model S12)
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:	Willow Wearable Breast Pump
510(k) Number:	K191577
Manufacturer:	Exploramed NC7, Inc.

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

6. Device Description

The Wearable Breast Pump (Model S12), is an electrically powered wearable single breast pump consisting of the following key components: a flange, linker, silicone diaphragm, pump motor, USB cable, valve, milk collector, and bra adjustment buckle. 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 to expression mode and control the vacuum levels within those modes. Both stimulation and expression mode consist of 9 vacuum levels. The S12 model is capable of providing vacuum levels from 40-105 mmHg with cycling rates from 75-109 cycles per minute in stimulation mode and vacuum levels from 40-245 mmHg with cycling rates from 28-85 cycles per minute in expression mode. The model S12 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 breast pump expresses 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) of the subject device are not in contact with the breast.

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 subject device components are made of the following materials:

- Motor unit: acrylonitrile-butadiene-styrene (ABS) plastic
- Flange, tube, valve, diaphragm: Silicone
- Linker, milk collection container: Polypropylene

All milk contacting components are compliant with 21 CFR 174-179.

7. Indications for Use

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.

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 S12 K212180 Subject Device	**Willow Wearable Breast Pump 2.0 K191577 Predicate Device**	**Comparison**
Product Name	Wearable Breast Pump	Willow Wearable Breast Pump	**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 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.	The Willow Wearable Breast Pump 2.0 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 or Double	**Different:** The difference in pump options do not raise different questions of safety and effectiveness.
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	7	**Different:** The differences in suction levels for each mode do not raise different questions of safety and effectiveness,
Adjustable suction levels	Yes	Yes	**Same**
Flange Size	24 mm and 27 mm	21 mm, 24 mm, and 27 mm	**Different:** The difference in flange sizes do not raise different questions of safety and effectiveness.
Vacuum range: Stimulation	-40 to -105 (±5) mmHg	-60 to -105 (±5) mmHg	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in maximum suction pressure were substantiated by performance testing below.
Vacuum range: Expression	-40 to -245 (±5) mmHg	-60 to -245 (±5) mmHg	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in maximum suction pressure were substantiated by performance testing below.
Cycle Speed: Stimulation	70 to 114 cycles/minute	90 cycles/minute	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in cycle speed were substantiated by performance testing below.
Cycle Speed: Expression	23 to 90 cycles/minute	60 cycle/minute	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in cycle speed were substantiated by performance testing below.
Controls	On/Off button; Mode selection Increase/decrease vacuum button;	On/Off button; Increase/decrease vacuum button	**Similar:** The subject and predicate have similar controls. Differences in controls do not raise different questions of safety and effectiveness.
Power Supply	Li-Ion Battery	Li-Ion Battery	**Same**
Indicators	Yes, LED	Yes	**Similar:** The subject device has an LED display. Differences in visual indicators do not raise different questions of safety and effectiveness.
Materials	Milk Container: Polypropylene Flange: Silicone Pump Outer Housing: Acrylonitrile Butadiene Styrene (ABS) plastic	Milk Container: Co-polymer polypropylene and silicone Flange: Polypropylene (grade changed) and silicone Pump Outer Housing: Polycarbonate and Thermoplastic polyurethane	**Different:** The subject and predicate devices are comprised of different materials. Differences in composition do not raise different questions of safety and effectiveness.

The indications for use of the subject and predicate device are identical.

The subject and predicate devices have similar technological features, including device design, user interface, overall vacuum pressure range, cycle speeds, materials, and power source. The different technological characteristics of the subject device do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including Skin Irritation Testing, Cytotoxicity, and Skin Sensitization testing were performed in accordance with the 2020 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"* and ISO 10993- 1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Skin Sensitization (ISO 10993-10:2010)
- Skin Irritation (ISO 10993-10:2010)

The testing supports the biocompatibility of the device. The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

Electrical Safety

Testing was conducted in accordance with AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD), 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 as recommended in the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

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.