July 14, 2023

Shenzhen TPH Technology Co., Ltd.
Peter Chen
General Manager
5th floor, Lianchuang 2nd technology Park, Bulan Road
Nanwan Community, Longgang District
Shenzhen, Guangdong 518100
China

Re: K223886
Trade/Device Name: Wearable Breast Pump (Model S18)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: June 13, 2023
Received: June 13, 2023

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,

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)*
K223886

Device Name
Wearable Breast Pump Model S18)

Indications for Use *(Describe)*
The Wearable Breast Pump (Model S18) 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 – K223886

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter Information

Applicant: Shenzhen TPH Technology Co., Ltd.

Contact: Peter Chen

Phone: +86-755-82703212

Address: 5th floor, Building NO.29 East side, Lianchuang 2nd technology Park, Longgang District, Shenzhen, China.

2. Date Prepared: July 13, 2023

3. Device Information:

Device Name: Wearable Breast Pump (Model S18)

Common Name: Powered Breast Pump

Regulation Number: 21 CFR 884.5160

Regulation Name: Powered Breast Pump

Product Code: HGX (Powered, Breast, Pump)

Regulatory Class: Class II

4. 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.

5. Device Description

The Wearable Breast Pump (Model S18) is designed for lactating woman to express and collect milk from the breast. It is an electrically powered, software-controlled, digital single user pump. The device consists of the following key components: flange, pump motor, silicone diaphragm, USB cable, milk collector, bra adjustment buckle, and valve. 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.

There are two modes, with multiple suction levels for each mode, available for the device: Expression mode and Stimulation mode. Both modes consist of nine vacuum levels. Expression mode consists of pressures ranging from 120-245 mmHg and cycle speeds of 20-66 cycles/min and stimulation mode consists of ranges from 40-120 mmHg and cycle speeds of 69-92 cycles/min. There is an LED status display shown on the pump body, which displays the working mode and battery indicator.

The device may be operated as a single or double pumping system. For a user to pump both breasts simultaneously, they would need to use two 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 should not be used while charging.

The device 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 S18) is intended to express milk from lactating women in order to collect milk from their breasts. The device 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

	Proposed Device Wearable Breast Pump Model S18 K223886	**Predicate Device Wearable Breast Pump Model S12 K212180**	**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 S18) 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
Patient Population	Lactating women	Lactating women	Same
Single user	YES	YES	Same
Single/double pump	Single	Single	Same
Backflow Protection	YES	YES	Same
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor	Same
Specifications			
Power Supply	Li-ion battery	Li-ion battery	Same
Suction Modes	Stimulation and Expression	Stimulation and Expression	Same
Suction Strength (Stimulation)	40-120 mmHg	40-105 mmHg	Different
Cycle Speed: Stimulation	69 to 92 cycles/minute	70 to 114 cycles/minute	Different
Suction Strength (Expression)	120-245 mmHg	40-245 mmHg	Different
Cycle Speed: Expression	20 to 66 cycles/minute	23 to 90 cycles/minute	Different
Suction levels	9	9	Same
User interface			
User control	On-off switch, vacuum adjustment	On-off switch, vacuum adjustment	Same
Adjustable suction levels	YES	YES	Same

Wireless technology	No	No	Same
Component design	Milk collector and flange	Milk collector and flange	Same
Milk collector Capacity	180 ml	180ml	Same
Flange size	21mm, 24mm, and 27mm	24mm and 27mm	Different
Material			
Milk collector/Linker	Polypropylene	Polypropylene	Same
Flange/Valve/ Diaphragm	Silicone	Silicone	Same
Pump motor/outer housing	ABS	ABS	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 pumping options, control mechanism, user interface, backflow protection, and device indicators. However, as shown in the table above, there are technological differences between the subject and predicate devices, including different vacuum and cycle specifications and flange sizes. The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

8. Summary of Non-Clinical Performance Testing

Biocompatibility

The materials of the subject device are identical to K212180 in formulation, processing, and cleaning. Therefore, biocompatibility information from K212180 was leveraged to support the biocompatibility of patient-contacting components of the subject device.

Electrical Safety and Electromagnetic Compatibility (EMC)

Testing was conducted in accordance with ANSI/AAMI ES60601-1:2005 + A1:2012, *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*.

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 disturbances – Requirements and Tests.*

Software

Software was evaluated for a moderate level of concern as recommended in the 2005 FDA guidance document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*

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 at each mode/cycle demonstrated that the device meets 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 functions 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.

9. Conclusion

The results of the performance testing described above demonstrate that the Wearable Breast Pump (Model S18) is as safe and effective as the predicate device and supports a determination of substantial equivalence.