



January 4, 2023

Shenzhen TPH Technology Co.,Ltd.
% Carmen Zhang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Liuxian Avenue, Xili Town, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K222045
Trade/Device Name: Wearable Breast Pump (Model S1DW)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: November 30, 2022
Received: December 5, 2022

Dear Carmen Zhang:

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,


Michael T. Bailey -S

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

Indications for Use

510(k) Number (if known)

K222045

Device Name

Wearable Breast Pump (Model S1DW)

Indications for Use (Describe)

The Wearable Breast Pump (Model S1DW) 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K222045

1. Submitter Information

Applicant: Shenzhen TPH Technology Co., Ltd.
Contact: Peter Chen
Phone: + 86 (400) 788-9005
Email: peter@tph-tech.com
Address: 5th Floor, Building No.29 East side,
Lianchuang 2th technology park, Bulan
Road, Nanwan Community, Longgang
District, Shenzhen, China

2. Correspondent Information

Contact: Carmen Zhang
Consultant
Firm: Shenzhen Joyantech Consulting
Phone: + 86 (755) 860-69197
Email: carmen@cefd.com

3. Date prepared: January 3, 2023

4. Device Information

Device Name:	Wearable Breast Pump (Model S1DW)
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:	Electric Breast Pump
510(k) Number:	K211755
Manufacturer:	Zhejiang Carebao Co., Ltd.

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

6. Device Description

The Wearable Breast Pump (Model S1DW) is an electrically powered wearable single or double breast pump consisting of the following key components: a flange, linker, silicone diaphragm, pump motor, USB charging cable, silicone tubing, 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) or two breasts (double 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 S1DW model is capable of providing vacuum levels from 40-120 mmHg with cycling rates from 38-51 cycles per minute in stimulation mode and vacuum levels from 120-245 mmHg with cycling rates from 19-40 cycles per minute in expression mode. The model S1DW Wearable Breast Pump is charged with a 5 V DC USB 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 non-sterile.

The breast pump expresses breast 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) 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 using 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, tubing, 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 S1DW) 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 S1DW) K222045 Subject Device	Electric Breast Pump K211755 Predicate Device	Comparison
Product Name	Wearable Breast Pump (Model S1DW)	Electric 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 S1DW) 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 electric breast pump is intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.	Same Intended Use
Pump Options	Single or Double	Single or Double	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same

Backflow Protection	Yes	Yes	Same
Mobile Application	No	No	Same
Suction Modes	Stimulation Mode and Expression Mode	Stimulation Mode and Expression Mode	Same
Suction levels	9 Stimulation, 9 Expression	YD-1130S: 5 stimulation, 9 expression YD-1132S: 6 stimulation, 9 expression YD-1168: 5 stimulation, 9 expression	Different- Differences in the number of suction levels for each mode do not raise different questions of safety and effectiveness (S&E).
Adjustable suction levels	Yes	Yes	Same
Vacuum range: Stimulation	-40 to -120 (± 5) mmHg	YD-1130S: 34-190 mmHg YD-1132S: 34-280 mmHg YD-1168: Single pumping: 34-190 mmHg Double pumping: 89-190 mmHg	Different- The vacuum ranges of the subject and predicate devices are not the same, including a lower maximum vacuum pressure for the subject device. Differences in vacuum specifications do not raise different questions of S&E.
Vacuum range: Expression	-120 to -245 (± 5) mmHg	YD-1130S: 67-280 mmHg YD-1132S: 97-280 mmHg YD-1168: Single pumping: 87-280 mmHg Double pumping: 96-280 mmHg	Different - The vacuum ranges of the subject and predicate devices are not the same, including a lower maximum vacuum pressure for the subject device. Differences in vacuum specifications do not raise different questions of S&E.
Cycle Speed: Stimulation	38 to 45 (± 2) cycles/minute for double pumping 45 to 51 (± 2) cycles/minute for single pumping	YD-1130S: 40-140 cycles/min YD-1132S: 10-140 cycles/min YD-1168: Single pumping: 52-140 cycles/min Double pumping: 63-105 cycles/min	Different - The cycle speed ranges of the subject and predicate devices are not the same, including lower maximum cycle speeds for the subject device. Differences in cycle speed specifications do not raise different questions of S&E.
Cycle Speed: Expression	19 to 34 (± 2) cycles/minute for double pumping 22 to 40 (± 2) cycles/minute for single pumping	YD-1130S: 24-70 cycles/min YD-1132S: 21-68 cycles/min YD-1168: Single pumping: 25-78 cycles/min Double pumping: 28-83 cycles/min	Different - The cycle speed ranges of the subject and predicate devices are not the same, including lower maximum cycle speeds for the subject device. Differences in cycle speed specifications do not raise different questions of S&E.
Controls	On/Off button; Mode selection Increase/decrease vacuum button; Double/dingle pumping	On/Off button; Mode selection Increase/decrease vacuum button; Double/Single Pumping	Similar: Both devices have push button interfaces on their motor units. Minor differences in visual indicators do not raise different questions of safety and effectiveness.
Power Supply	Li-Ion Battery	Li-Ion Battery or AC Power	Different – The subject device is only battery-operated, while the predicate device can be operated by battery or mains power. This difference does not raise different questions of S&E.
Indicators	Yes, LED	Yes, LED	Same

The indications for use of the subject and predicate device are comparable, 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 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 device, including vacuum and cycle specifications, power supply, and vacuum levels. 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 studies, including irritation, cytotoxicity, and 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"*, as follows:

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

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

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 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 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.