



July 28, 2025

Shenzhen TPH Technology Co., Ltd.
Xiaoyan Yang
Quality Engineer
Room 203, 2nd floor, 29th Building, Lianchuang Technology
Park, No. 21 Bulan Road
Shenzhen, Guangdong 518100
CHINA

Re: K250843
Trade/Device Name: Wearable Breast Pump (Model FS12A);
Wearable Breast Pump (Model FS12B)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: Class II
Product Code: HGX
Dated: March 10, 2025
Received: July 3, 2025

Dear Xiaoyan Yang:

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.

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, 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)

K250843

Device Name

Wearable Breast Pump (Model FS12A); Wearable Breast Pump (Model FS12B)

Indications for Use (Describe)

The Wearable Breast Pump (Model FS12A); Wearable Breast Pump (Model FS12B) are powered breast pumps intended to be used by lactating women to express and collect milk from their breasts. They are intended for a single user only.

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 – K250843

1. Submitter Information

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2. Correspondent Information

Contact: Yang Xiaoyan
Quality Engineer
Shenzhen TPH Technology Co., Ltd.
Email: yangxiaoyan@tph-tech.com

3. Date prepared: July 30, 2025

4. Device Information

Device Name:	Wearable Breast Pump (Model FS12A); Wearable Breast Pump (Model FS12B)
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 FS12A); Wearable Breast Pump (Model FS12B) are powered breast pumps intended to be used by lactating women to express and collect milk from their breasts; they are intended for a single user. Both Wearable Breast Pump (Model FS12A) and Wearable Breast Pump (Model FS12B) are breast pumps powered by lithium battery, utilizing an embedded control program to manage all device functions. The main components of these pumps include: Pump, valve, control board, and milk collector. The user interface allows the user to switch from stimulation, expression, and auto modes and control the vacuum levels within those modes.

All available modes consist of 12 vacuum levels. The Wearable Breast Pump (Model FS12A); Wearable Breast Pump (Model FS12B) are capable of providing vacuum levels from 40-160 mmHg with cycling rates from 75-133 cycles per minute in stimulation mode, vacuum levels from 120-245 mmHg with cycling rates from 21-98 cycles per minute in expression mode, and vacuum levels from 40-245 mmHg with cycling rates from 21-150 cycles per minute in auto mode. The Wearable Breast Pump (Model FS12A); Wearable Breast Pump (Model FS12B) 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 devices are for repeated use by a single user in a home environment. The devices are provided non-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 devices 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 FS12A); Wearable Breast Pump (Model FS12B) are powered breast pumps intended to be used by lactating women to express and collect milk from their breasts. They are intended for a single user only.

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 FS12A); Wearable Breast Pump (Model FS12B) K250843 Subject Device	Wearable Breast Pump (Model S12) K212180 Predicate Device	Comparison
Product Name	Wearable Breast Pump (Model FS12A); Wearable Breast Pump (Model FS12B)	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 FS12A); Wearable Breast Pump (Model FS12B) are powered breast pumps intended to be used by lactating women to express and collect milk from their breasts. They are intended for a single user only.	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.	Similar
Pump Options	Single	Single	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same

Backflow Protection	Yes	Yes	Same
Suction Modes	Stimulation Mode, Expression Mode, Auto Mode	Stimulation Mode and Expression Mode	Different
Suction levels	12	9	Different
Adjustable suction levels	Yes	Yes	Same
Vacuum range: Stimulation	-40 to -160 (± 5) mmHg	-40 to -105 (± 5) mmHg	Different
Vacuum range: Expression	-120 to -245 (± 5) mmHg	-40 to -245 (± 5) mmHg	Different
Vacuum range: Auto	-40 to -245 (± 5) mmHg	N/A	Different
Cycle Speed: Stimulation	75 to 133 (± 2) cycles/minute	70 to 114 cycles/minute	Different
Cycle Speed: Expression	21 to 98 (± 2) cycles/minute	23 to 90 cycles/minute	Different
Cycle Speed: Auto	21 to 150 (± 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
Design	Wearable pump with combined Milk Collector and Flange	Wearable pump with combined Milk Collector and Flange	Same

The indications for use of the subject and predicate devices are similar, and both devices 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 devices, including different overall vacuum/cycle specifications and available modes. The different technological characteristics of the subject devices, 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 leveraged from the predicate device and was 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."*

Electrical Safety

Testing was leveraged from the predicate device and was conducted in accordance with IEC 60601- 1 Edition 3.2 2020-08 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 Edition 3.1 2020-07 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 leveraged from the predicate device and was conducted in accordance with IEC 60601-1-2:2014+A1: 2020 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 devices meet their 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 devices maintain their 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 results of the performance testing described above demonstrate that Wearable Breast Pump (Model FS12A); Wearable Breast Pump (Model FS12B) are as safe and effective as the predicate device and support a determination of substantial equivalence.