July 24, 2026

Shenzhen TPH Technology Co., Ltd.
Dale Wang
Regulatory Affairs Engineer
Rm. 203, 2nd Floor, 29th Bldg., Lianchuang Technology Park
21 Bulan Rd., Xialilang Community, Nanwan St. Longgang Dis
Shenzhen, 518000
China

Re: K260259
Trade/Device Name: DiscreetDuo™ Flow Wearable Breast Pump (Model S3)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: June 24, 2026
Received: June 25, 2026

Dear Dale Wang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260259

Device Name
DiscreetDuo™ Flow Wearable Breast Pump (Model S3)

Indications for Use *(Describe)*
The DiscreetDuo™ Flow Wearable Breast Pump (Model S3) is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It 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 – K260259

1. Submitter

Company: Shenzhen TPH Technology Co., Ltd.

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Contact Person

Name: Dale WANG

Position Title: Regulatory Affairs Engineer

Company: Shenzhen TPH Technology Co., Ltd.

Tel.: 86-19129492601

Email: dale@tph-tech.com

Date Prepared

July 22, 2026

2. Device Information

Device Name: DiscreetDuo™ Flow Wearable Breast Pump (Model S3)

Common Name: Powered breast pump

Regulation Number: 21 CFR 884.5160

Regulation Name: Powered breast pump

Product Code: HGX (Pump, Breast, Powered)

Classification Panel: Obstetrics/Gynecology

Regulatory Class: Class II

3. Predicate Device Information

Manufacturer: Shenzhen TPH Technology Co., Ltd.

Predicate Device Name: Wearable Breast Pump (Model S32)

Model: S32

510(k) Number: K240536

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

4. Device Description

The DiscreetDuo™ Flow Wearable Breast Pump (Model S3) is a wearable powered breast pump designed for lactating woman to express and collect milk from the breast.

There are 4 modes available for the device which are Stimulation mode, Expression mode, Massage mode, and Auto mode. There is an LED status display for S3, including working mode, and battery indicator can be shown on the pump body. The user interface includes on/off switch, mode selection/short press, and vacuum adjustment.

S3 can be operated as a single or double pumping system, one on each breast. The pump is provided non-sterile and reusable by a single user. The device is powered by a rechargeable Li-ion battery (3.7V, 1500mAh). Model S3 is designed not to be used during charging.

The breast pump does not incorporate any off-the-shelf (OTS) software. 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 which is applicable for the subject device.

5. Indications for Use

The DiscreetDuo™ Flow Wearable Breast Pump (Model S3) is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.

6. Comparison of Intended Use and Technological Characteristics of the Subject Device and Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 1. Comparison to Predicate Device

Item	**Subject Device** DiscreetDuo™ Flow Wearable Breast Pump (Model S3)	**Predicate Device** Wearable Breast Pump (Model S32) **K240536**	**Comment**
Device Classification Name	Pump, Breast, Powered	Pump, Breast, Powered	Same
Classification	Class II	Class II	Same
Regulation No.	21 CFR 884.5160	21 CFR 884.5160	Same
Product Code	HGX	HGX	Same
Indications for Use	The DiscreetDuo™ Flow Wearable Breast Pump (Model S3) is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.	The Wearable Breast Pump (Model S32) is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.	Same
Patient Population	Lactating women	Lactating women	Same
Anatomical Sites	Breast	Breast	Same
Single User	YES	YES	Same
Single/Double Pump	Single	Single	Same
Media Separation (Backflow Protection)	YES	YES	Same
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor	Same
Suction Modes	Stimulation mode, expression mode, massage mode, and auto mode	Stimulation mode and expression mode	Different

Specifications			
Power Supply	Li-ion battery	Li-ion battery	Same
Suction Strength (Stimulation mode)	40-160 mmHg	40-120 mmHg	Different
Suction Strength (Expression mode)	120-245 mmHg	120-245 mmHg	Similar
Suction Strength (Massage mode)	40-120 mmHg	40-120 mmHg	Similar
Suction Strength (Auto mode)	40-245 mmHg	40-245 mmHg	Similar
Cycle Speed (Stimulation mode)	93-138 cycles/minute	86-110 cycles/minute	Different
Cycle Speed (Expression mode)	32-106 cycles/minute	33-109 cycles/minute	Different
Cycle Speed (Massage mode)	95-153 cycles/minute	90-120 cycles/minute	Different
Cycle Speed (Auto mode)	31-153 cycles/minute	33-120 cycles/minute	Different
Suction Levels	9	9	Same
User Interface			
User Control	On-Off switch, vacuum adjustment, mode change/power，Night light switch	On-Off switch, vacuum adjustment, mode change/power	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 device are identical, and they have the same intended use (i.e., for collection of breast milk from the breasts of lactating women).

As seen in the comparison table, the subject and predicate devices have different technological features, including the user interface, suction strength, cycle speed range, and suction levels. These technological differences do not raise different questions of safety and effectiveness.

7. Summary of Non-Clinical Performance Testing

The following performance data were provided in support of the substantial equivalence determination:

Performance and Use Life Verification

Bench performance testing was conducted to demonstrate that the device meets its design requirements and performs as intended. These 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.

-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.

-Use life testing was conducted to demonstrate that the device maintains its specifications throughout its proposed use life.

Biocompatibility Testing

The biocompatibility evaluation for the Wearable Breast Pump was conducted 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," as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2021)
- Irritation (ISO 10993-23:2021)

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Wearable Breast Pump device, consisting of all the modules and accessories in the system. The system complies with the following standards:

- IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance

- 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

- IEC 60601-1-2:2014/A1:2021 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements

and tests standard for EMC

- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Software Verification and Validation Testing

Software verification and validation was conducted as recommended in the 2023 FDA guidance document, "Content of Premarket Submissions for Device Software Functions" with a Basic Documentation Level.

8. Substantial Equivalence Conclusion:

The results of the performance testing described above demonstrate that the DiscreetDuo™ Flow Wearable Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.