July 15, 2025

Shenzhen TPH Technology Co., Ltd.
Yang Xiaoyan
Quality Engineer
Room 203, 2nd floor, 29th Building,
Lianchuang Technology Park, No.21 Bulan Road, Xialilang Community,
Nanwan Street, Longgang District,
Shenzhen, Guangdong 518100
China

Re: K250350
Trade/Device Name: Thrive 2-in-1 Breast Pump (Model P3)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: June 16, 2025
Received: June 16, 2025

Dear Yang Xiaoyan:

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,

Reginald K. Avery -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

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)*
K250350

Device Name
Thrive 2-in-1 Breast Pump (Model P3)

Indications for Use *(Describe)*
The Thrive 2-in-1 Breast Pump, Model P3 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 – K250350

1. Submitter:

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Tel.: +86-755-82703212

Contact Person - Xiaoyan Yang, Quality Engineer

Shenzhen TPH Technology Co., Ltd.

yangxiaoyan@tph-tech.com

Date Prepared - July 14, 2025

2. Device name and Classification:

Device Name: Thrive 2-in-1 Breast Pump（Model P3)

Common Name: Powered Breast Pump

Regulation Number: 21 CFR 884.5160

Regulation Name: Powered Breast Pump

Product code: HGX

Regulatory Class: II

3. Predicate Device Information:

Device Name: Lucy Breast Pump

510(k) Number: K213311

Manufacturer: Willow Innovations, Inc.

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

4. Device Description

Thrive 2-in-1 Breast Pump (Model P3) is a wearable powered breast pump intended to be used by lactating women to express and collect milk from the breast. It is an electrically powered, software-controlled, digital pump. It is powered by a lithium ion battery (3.7 V, 2000 mAh) and utilizes an embedded control program to manage all product functions. The device is designed not to be used during charging.

The main components of this pump include pump, valve, flange and flange body, silicone diaphragm, USB charging cable, tubing with y-connector, bra extension strap and collection cups. The pump is provided non-sterile and reusable by a single user.

There are two (2) operating modes available for the device - Expression mode and Massage mode, with two frequency options – “High” and “Low” within each operating mode. The subject device includes nine (9) suction levels within each mode of operation. The Expression mode has a suction pressure range of 60 -245 mmHg and cycle frequency in the range 17-50 (High)/15-36 (Low) cycles per minute while Massage mode has a suction pressure range of 60-130 mmHg and cycle frequency range of 38-52 (High)/28-36 (Low) cycles per minute. The subject device has an LED status display, which displays

working mode and battery indicator. The user interface includes power on/off/pause switch, mode/frequency switch, vacuum level adjustment buttons (up and down). The subject device is intended only for double pumping, with one collection cup intended for each breast.

The breast pump does not incorporate any off-the-shelf (OTS) software. All milk contacting components of the device are compliant with 21 CFR 177.

5. Indications for Use

The Thrive 2-in-1 Breast Pump, Model P3 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. Predicate Device Comparison

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** Thrive 2-in-1 Breast Pump (Model P3) (K250350)	**Predicate Device** Lucy Breast Pump (K213311)	**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 Thrive 2-in-1 Breast Pump, Model P3 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 Lucy Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Lucy Breast Pump is intended for a single user.	Similar
Single-User	Yes	Yes	Same
Single/double pump	Double	Single or Double	**Different**
Backflow Protection	Yes	Yes	Same
User Interface	On/off /pause button, mode/frequency selection button, suction increase button, suction decrease button, LED display	On/off button mode button, suction increase button, suction decrease button, LED light	**Different**
Power Source	Rechargeable Li-Ion battery	Rechargeable Li-Ion battery	**Different**
Control Mechanism	Microprocessor	Microprocessor	Same
Pump Type	Diaphragm-type wearable	Diaphragm-type wearable	Same
Specifications			
Maximum Vacuum (mmHg)	-250	-295	**Different**
Vacuum Range (mmHg)	Massage: -60 to -130 Expression: -60 to -245	-75 to -280	**Different**
Cycle Speed Range (cycles/minute)	Massage (High): 38-52 Massage (Low): 28-36 Expression (High): 17-50 Expression (Low): 15-36	30 - 100 cycles/minute	**Different**

The subject and predicate devices have similar Indications for Use statements and have the same

intended use (i.e., for collection of breast milk from the breasts of lactating women).

As noted in the comparison table above, the subject and predicate devices have technological differences, including differences in vacuum/cycle speed specifications, available modes/vacuum levels, user interface, and overall pump configurations. These differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

7. Performance Testing:

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)
- Skin Sensitization (ISO 10993-10:2021)
- Skin Irritation (ISO 10993-23:2021

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.
All milk contacting components of the device are compliant with 21 CFR 177.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device, including all 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 documentation including verification & validation was provided in accordance with 2023 FDA Guidance: *Content of Premarket Submissions for Device Software Functions*.

Performance and Use Life Verification

The following performance testing were conducted to demonstrate that the subject device meets its design specifications and performs as intended. The performance tests include:

- Vacuum level and cycle frequency verification testing at each mode/level demonstrated that the device meets the mode/level 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 including adequate battery capacity, battery status indicator, and

charging/discharging time.

8. Substantial Equivalence Conclusion:

The results of the performance testing described above demonstrate that the Thrive 2-in-1 Breast Pump (Model P3) is as safe and effective as the predicate device and supports a determination of substantial equivalence.