May 30, 2025

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

Re: K250365
Trade/Device Name: Motif Aura Glow breast pump (Model Motif Aura Glow)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: April 30, 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

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)*
K250365

Device Name
Motif Aura Glow breast pump (Model Motif Aura Glow)

Indications for Use *(Describe)*
The Motif Aura Glow breast pump (Model Motif Aura Glow) 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.

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
PRAStaff@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 – K250365

1. Submitter Information

Applicant: Shenzhen TPH Technology Co., Ltd.
Address: Room 203, 2nd floor, 29th Building, Lianchuang Technology Park, No.21 Bulan Road, Xialilang, Shenzhen, Guangdong 518100 CHN
Tel.: 86 (133) 024-76262
.

2. Correspondent Information

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

3. Date prepared: May 29, 2025

4. Device Information

Device Name:	Motif Aura Glow breast pump (Model Motif Aura Glow)
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 Motif Aura Glow breast pump (Model Motif Aura Glow) 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 Motif Aura Glow breast pump (Model Motif Aura Glow) is powered by a lithium battery, utilizing an embedded control program to manage all device functions. The main components of this pump include: Pump, valve, control board, and milk collector. The user interface allows the user to switch from massage, expression, cluster feeding, and general pumping modes and control the vacuum levels within those modes.

Massage, expression, and general pumping modes consist of 9 vacuum levels. Cluster feeding mode consists of 5 vacuum levels. The Motif Aura Glow breast pump (Model Motif Aura Glow) is capable of providing vacuum levels from 40-160 mmHg with cycling rates from 75-120 cycles per minute in massage mode, vacuum levels from 120-245 mmHg with cycling rates from 30-85 cycles per minute in expression mode, vacuum levels from 40-200 mmHg with cycling rates from 45-120 cycles per minute in cluster feeding mode, and vacuum levels from 60-245 mmHg with cycling rates from 30-120 cycles per minute in general pumping mode. The Motif Aura Glow breast pump (Model Motif Aura Glow) 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 device is for repeated use by a single user in a home environment. The device is provided not 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 device are not in contact with the breast. All milk contacting components are compliant with 21 CFR 174-179.

7. Indications for Use

The Motif Aura Glow breast pump (Model Motif Aura Glow) 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.

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

	Motif Aura Glow breast pump (Model Motif Aura Glow) K250365 Subject Device	**Wearable Breast Pump (Model S12) K212180 Predicate Device**	**Comparison**
Product Name	Motif Aura Glow breast pump (Model Motif Aura Glow)	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 Motif Aura Glow breast pump (Model Motif Aura Glow) 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 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, Cluster feeding Mode,	Stimulation Mode and Expression Mode	**Different**

	General Pumping Mode		
Suction levels	Cluster feeding mode – 5 Massage, Expression, General – 9	9	**Different**
Adjustable suction levels	Yes	Yes	**Same**
Vacuum range: Massage	-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: Cluster feeding	-40 to -200 (±5) mmHg	N/A	**Different**
Vacuum range: General Pumping	-60 to -245 (±5) mmHg	N/A	**Different**
Cycle Speed: Massage	75 to 120 (±2) cycles/minute	70 to 114 cycles/minute	**Different**
Cycle Speed: Expression	30 to 85 (±2) cycles/minute	23 to 90 cycles/minute	**Different**
Cycle Speed: Cluster Feeding	45 to 120 (±2) cycles/minute	N/A	**Different**
Cycle Speed: General Pumping	30 to 120 (±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 device are identical, and they have the same intended use (i.e., for collection of breast milk from the breasts of lactating women).

The subject and predicate device 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 device, including different overall vacuum/cycle specifications and available modes. 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 information was provided in accordance with Attachment G of 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 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 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 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 results of the performance testing described above demonstrate that The Motif Aura Glow breast pump (Model Motif Aura Glow) is as safe and effective as the predicate device and supports a determination of substantial equivalence.