



March 20, 2025

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

Re: K250463  
Trade/Device Name: Ameda GLO Wearable Breast Pump (Model W8S)  
Regulation Number: 21 CFR 884.5160  
Regulation Name: Powered Breast Pump  
Regulatory Class: II  
Product Code: HGX  
Dated: January 18, 2025  
Received: February 18, 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](mailto: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)

K250463

Device Name

Ameda GLO Wearable Breast Pump ( Model W8S )

Indications for Use (Describe)

The Ameda GLO Wearable Breast Pump ( Model W8S ) 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 – K250463

|                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b><u>1. Submitter:</u></b>                   | Shenzhen TPH Technology Co., Ltd.<br><br>Room 203, 2nd floor, 29th Building, Lianchuang Technology Park, No.21 Bulan Road,<br>Xialilang, Shenzhen, Guangdong 518100 CHN<br>Tel.: 86 (133) 024-76262                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b><u>Contact Person:</u></b>                 | Yang Xiaoyan<br><br>Quality Engineer<br><br>Shenzhen TPH Technology Co., Ltd.<br><br><a href="mailto:yangxiaoyan@tph-tech.com">yangxiaoyan@tph-tech.com</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b><u>Date Prepared:</u></b>                  | March 18, 2025                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b><u>2. Device Information:</u></b>          | <b>Device Name:</b> Ameda GLO Wearable Breast Pump (Model W8S)<br><b>Common Name:</b> Powered breast pump<br><b>Regulation Number:</b> 21 CFR 884.5160<br><b>Regulation Name:</b> Powered breast pump<br><b>Product code:</b> HGX (Pump, Breast, Powered)<br><b>Classification Panel:</b> Obstetrics/Gynecology<br><b>Regulatory Class:</b> Class II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b><u>3. Predicate Device Information</u></b> | Wearable Breast Pump (Model W8) cleared under <b>K242850</b> .<br><br>The predicate device has not been subject to a design-related recall.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b><u>4. Device Description:</u></b>          | <p>The Ameda GLO Wearable Breast Pump (Model W8S) is a wearable powered breast pump designed for lactating woman to express and collect milk from the breast. The device is an electrically powered, software-controlled, digital single user pump.</p> <p>There are 4 modes available for the device which are Expression mode, Massage mode, Auto mode and Stimulation mode. There is a LED status display for W8S, including working mode, and battery indicator can be shown on the pump body. The user interface includes on/off switch, mode selection/long press, and vacuum adjustment.</p> <p>Ameda GLO Wearable Breast Pump (Model W8S) 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 rechargeable Li-ion battery (3.7V, 1200mAh). W8 is designed not to be used during charging.</p> <p>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.</p> |

**5. Indications for Use:**

The Ameda GLO Wearable Breast Pump (Model W8S) 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**

| <b>Item</b>                            | <b>Proposed Device<br/>Ameda GLO Wearable Breast Pump (Model W8S)</b>                                                                                                                            | <b>Proposed Device<br/>Wearable Breast Pump (Model W8)</b>                                                                                                                            | <b>Comment</b> |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| 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 Ameda GLO Wearable Breast Pump (Model W8S) 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 W8) 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. | Similar        |
| 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           |
| <b>Specifications</b>                  |                                                                                                                                                                                                  |                                                                                                                                                                                       |                |
| Power Supply                           | Li-ion battery                                                                                                                                                                                   | Li-ion battery                                                                                                                                                                        | Same           |
| Suction Strength (Stimulation)         | 40-170 mmHg                                                                                                                                                                                      | 40-170 mmHg                                                                                                                                                                           | Same           |
| Cycle Speed: Stimulation               | 77 to 127 cycles/minute                                                                                                                                                                          | 77 to 127 cycles/minute                                                                                                                                                               | Same           |
| Suction Strength (Expression)          | 120-245 mmHg                                                                                                                                                                                     | 120-245 mmHg                                                                                                                                                                          | Same           |
| Cycle Speed: Expression                | 32 to 92 cycles/minute                                                                                                                                                                           | 32 to 92 cycles/minute                                                                                                                                                                | Same           |
| Suction Strength (Massage)             | 40-140 mmHg                                                                                                                                                                                      | 40-140 mmHg                                                                                                                                                                           | Same           |
| Cycle Speed: Massage                   | 79-143 cycles/minute                                                                                                                                                                             | 79-143 cycles/minute                                                                                                                                                                  | Same           |
| Suction Strength                       | 40-245mmHg                                                                                                                                                                                       | 40-245mmHg                                                                                                                                                                            | Same           |

|                              |                                                             |                                                  |           |
|------------------------------|-------------------------------------------------------------|--------------------------------------------------|-----------|
| (Auto)                       |                                                             |                                                  |           |
| Cycle Speed:<br>Auto         | 32-136 cycles/minute                                        | 32-136 cycles/minute                             | Same      |
| Suction levels               | 15                                                          | 15                                               | Same      |
| User interface (LED display) |                                                             |                                                  |           |
| User control                 | On-Off switch, mode selection/long press, vacuum adjustment | On-Off switch, mode selection, vacuum adjustment | Different |
| Adjustable suction levels    | YES                                                         | YES                                              | Same      |
| Wireless technology          | No                                                          | No                                               | Same      |
| Component design             | Milk collector and flange                                   | Milk collector and flange                        | Same      |
| Milk collector Capacity      | 180 ml                                                      | 180ml                                            | Same      |
| Flange size                  | 24mm and 27mm                                               | 24mm and 27mm                                    | Same      |
| Material                     |                                                             |                                                  |           |
| Milk collector/Linker        | Polypropylene                                               | Polypropylene                                    | Same      |
| Flange/Valve/Diaphragm       | Silicone                                                    | Silicone                                         | Same      |
| Pump motor/outer housing     | ABS                                                         | ABS                                              | Same      |

In comparison to the predicate device, the subject device has the same intended use and indications for use – the expression and collection of breast milk.

As seen in the comparison table, the subject and predicate devices have minor different technological features, including differences in the user interface. 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 and leveraged from K242850 to evaluate the following device performance:

- Vacuum pressure
- Cycle speed
- Backflow protection
- Battery capacity & service time
- Charging time

Device specifications were met for all tests conducted.

### **Biocompatibility testing**

The biocompatibility evaluation for the Ameda GLO Wearable Breast Pump (Model W8S) was leveraged from K242850 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 10993-10:2021)

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

#### **Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were leveraged from K242850, 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 were leveraged from K242850 and 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 Ameda GLO Wearable Breast Pump (Model W8S) is as safe and effective as the predicate device and supports a determination of substantial equivalence.