August 30, 2024

Dongguanshi Yiyingmei Technology Co., Ltd.
Chen Jian
Quality Manager
Room 701, No. 31 Tangxi Street Shatou, Chang'an Town
Donguang, Guangdong 523000
CHINA

Re: K231969
Trade/Device Name: BASEN™ Wearable Breast Pump (Model: YM-801, YM-803, YM-805, YM-806, YM-808)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: August 1, 2024

Dear Chen Jian:

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.

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: 06/30/2023
See *PRA Statement below.*

Submission Number *(if known)*

K231969

Device Name

BASEN™ Wearable Breast Pump (YM-801,YM-803,YM-805,YM-806,YM-808)

Indications for Use *(Describe)*

The BASEN™ Wearable Breast Pump (Model: YM-801, YM-803, YM- 805, YM-806, YM-808) is intended to express milk from lactating women in order to collect milk from their breasts. The device 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.

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510(k) Summary – K231969
Dongguanshi Yiyingmei Technology Co., Ltd.
Wearable Breast Pump (Model YM-801, YM-803, YM-805, YM-806, YM-808)

1. Submitter Information

Applicant	Dongguanshi Yiyingmei Technology Co., Ltd.
Address	Room 701, No. 31 Tangxi Street Shatou, Chang'an Town, Dongguan City, 523000 Guangdong Province, China
Contact person	Chen Jian
Tel	+86-13612905723
Email	orchard.chan@qq.com
Date Prepared	July 8, 2024

2. Subject Device Information

Proprietary Name	BASEN™ Wearable Breast Pump
Common Name	Powered Breast Pump
Model	Model: YM-801, YM-803, YM-805, YM-806, YM-808
Regulation Name	Powered Breast Pump
Regulation Number	21 CFR§ 884.5160
Product Code	HGX (Pump, Breast, Powered)
Regulation Number	21 CFR§ 884.5160
Regulatory Class	II

3. Predicate Device

Manufacturer	Shenzhen TPH Technology Co., Ltd.
510(k) Number	K212180
Trade/Device Name	Wearable Breast Pump

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

4. Indications for Use

The BASEN™ Wearable Breast Pump (Model: YM-801, YM-803, YM- 805, YM-806, YM-808) is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.

5. Device Description

The BASEN™ Wearable Breast Pump is an electrically powered wearable breast pump consisting of the following key components: pump, pump diaphragm, container valve, 5-ounce (150

milliliter) container bowl, flange, seal ring, joint pipe, and USB charging cable. It is designed to work in the user's bra and has a rechargeable battery so it can be used hands-free without any external power cords. The motor unit includes a press-button user interface, pump body, and LED display. Pumping can be performed on one breast (single pumping). The user interface allows the user to switch from stimulation, massage mode, and expression mode and control the vacuum levels within those modes.

Both stimulation and expression mode consist of 9 vacuum levels. The pump can provide vacuum levels from -40 to -105 mmHg with cycling rates from 70 to 114 cycles per minute in stimulation and massage mode. Expression mode had vacuum levels from -40 to -245 mmHg with cycling rates from 23 to 90 cycles per minute.

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 breast pump expresses 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 bowl. To prevent milk from flowing into the vacuum system, a backflow protection membrane physically separates the milk-contacting pathway from the vacuum system. 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 subject device components are made of the following materials:

- Motor unit: Acrylonitrile Butadiene Styrene (ABS) plastic
- Flange, tube, valve, diaphragm: Silicone
- Linker, milk collection container: Polypropylene

All milk contacting components are compliant with 21 CFR 174-179.

6. Comparison of Intended Use and Technological Characteristics

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

Table 1: Comparator Table for Subject Device and Predicate Device

	Subject Device	**Predicate Device**	**Comparison**
510(K) Number	**K231969**	**K212180**	**/**
Product Name	BASEN™ Wearable Breast Pump (Model: YM-801, YM-803, YM-805, YM-806, YM-808)	Wearable Breast Pump (Model S12)	/
Manufacturer	Dongguanshi Yiyingmei Technology Co., Ltd.	Shenzhen TPH Technology Co., Ltd.	/
Product Code	HGX	HGX	/
Regulation Class	Class II	Class II	Same
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	Same
Indications for Use	The BASEN™ Wearable Breast Pump (Model: YM-801, YM-803, YM- 805, YM-806, YM-808) is intended to express milk from lactating women in order to collect milk from their breasts. The device 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.	Same
Patient Population	Lactating Women	Lactating Women	Same
Pump Options	Single	Single	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Suction Modes	Stimulation Mode, Massage Mode, and Expression Mode	Stimulation Mode and Expression Mode	Different
Suction levels	9	9	Same
Adjustable suction levels	Yes	Yes	Same
Flange Size	24 mm and 27 mm	24 mm and 27 mm	Same
Vacuum range *Stimulation*	-40 to -105 (±5) mmHg	-40 to -105 (±5) mmHg	Same

Vacuum range *Expression*	-40 to -245 (±5) mmHg	-40 to -245 (±5) mmHg	Same
Vacuum range *Massage*	-40 to -105 (±5) mmHg	N/A	Different
Cycle Speed *Stimulation*	70 to 114 cycles/minute	70 to 114 cycles/minute	Same
Cycle Speed *Expression*	23 to 90 cycles/minute	23 to 90 cycles/minute	Same
Cycle Speed *Massage*	70 to 114 cycles/minute	N/A	Different
Controls	On/Off button; Mode selection Increase/decrease vacuum button;	On/Off button; Mode selection Increase/decrease vacuum button;	Same
Power Supply	Li-Ion Battery	Li-Ion Battery	Same
Indicators	Yes, LED	Yes, LED	Same
Materials	-Motor unit: Acrylonitrile Butadiene Styrene (ABS) plastic -Tube, valve, diaphragm: Silicone -Linker, milk collection container: Polypropylene	-Milk Container: Polypropylene -Flange: Silicone -Pump Outer Housing: Acrylonitrile Butadiene Styrene (ABS) plastic	Same

The subject and predicate devices have similar technological features, including device design, overall vacuum pressure range, cycle speeds, materials, and power source. The different technological characteristics of the subject device do not raise different questions of safety and effectiveness.

7. Non-Clinical Performance Testing

Biocompatibility

This device meets the recommendations of Attachment G of the 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" (issued September 2023). Therefore, this device is considered biocompatible.

Electrical Safety

Testing was conducted in accordance with IEC 60601-1:2005+A1:2012+A2:2020- Part 1: General

requirements for basic safety and essential performance, and IEC 60601-1-11:2015/AMD1:2020 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+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 a basic documentation level as recommended in the 2023 FDA guidance document "G*uidance for the Content of Premarket Submissions for device software function*."

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.

8. Conclusion

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