September 21, 2023

Huizhou LVB Maternal And Infant Supplies Co,Ltd.
Rain Yip
Registration Engineer
Block A 16 Huifengxi 3rd, Pingnan Industry Zone, Zhongkai
H-i-tech District
Huizhou, Guangdong 516000
China

Re: K230102
Trade/Device Name: Wearable Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: August 17, 2023
Received: August 21, 2023

Dear Rain Yip:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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.

510(k) Number *(if known)*
K230102

Device Name
Wearable Breast Pump

Indications for Use *(Describe)*
Wearable Breast Pump is a powered breast pump to be used by lactating women to express and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) summary – K230102

Date Prepared: September 20, 2023

I Submitter

Applicant: HuiZhou LVB Maternal and Infant Supplies Co., Ltd.
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II Proposed Device

Device Name:	Wearable Breast Pump (Model: ABP-1508)
Common Name:	Powered breast pump
Regulation Number:	21 CFR 884.5160
Regulation Name:	Powered Breast Pump
Regulatory Class:	Class II
Product code:	HGX (Pump, Breast, Powered)

III Predicate Devices

510(k) Number:	K212180
Trade name:	Wearable Breast Pump (Model S12)
Manufacturer:	Shenzhen TPH Technology Co., Ltd.

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

IV Device description

The Wearable Breast Pump is an electrically powered, software controlled, digital, single user, wearable breast pump for lactating women to express and collect milk from the breast. The subject device is capable of expression and stimulation modes, with nine associated suction levels for each. The vacuum pressure ranges from 80-200 mmHg for stimulation mode and 90-240 mmHg for expression mode. The device is powered by a rechargeable battery or a power adapter.

The device has an LED display, which shows the power button, pumping mode, suction level, timer, and battery charge level. Surrounding the front panel display are soft-touch

buttons allowing the user to power the device on/off, switch between stimulation and expression modes, and control the vacuum strength.

The breast pump expresses by creating a seal around the nipple using the flange and applying and releasing suction to the breast. The milk is collected in a milk collection container. To prevent milk from flowing into the vacuum system, a backflow protection membrane physically separates the milk-contacting pathway from the vacuum system.

The subject device components are made of the following materials:
•Valve: Silicone
•Breast shield, bottle, suction cap: Polypropylene

V Indication for use

Wearable Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The device is intended for a single user.

VI Comparison of technological characteristics with the predicate device

Item	Subject Device	Predicate Device (K212180)	Comparison
Product name	Wearable Breast Pump (ABP-1508)	Wearable Breast Pump (Model S12)	N/A
Product code	HGX	HGX	same
Regulation No.	21 CFR 884. 5160	21 CFR 884. 5160	same
Class	Class II	Class II	same
Indication for use	Wearable Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The device is intended for a single user.	The powered Electric Double Breast Pumps are intended to express and collect milk from the breast of a lactating woman. They are double pumps with a single pumping option and intended for single user.	same
Pumping options	Single	Single	same

HuiZhou LVB maternal and infant supplies Co.,Ltd.
510(k) Summary

Item	Subject Device	Predicate Device (K212180)	Comparison
Cycling control Mechanism	Microcontroller	Microcontroller	same
Suction modes	Stimulation Mode and Expression Mode	Stimulation Mode and Expression Mode	same
Suction levels	9	9	same
Adjustable suction levels	Yes	Yes	same
Flange size	21, 24, mm and 27 mm	24 mm and 27 mm	Different
Vacuum range: Stimulation	-80 to -200 (±5) mmHg	-40 to -105 (±5) mmHg	Different: The difference in vacuum range do not raise different questions of safety and effectiveness.
Vacuum range: Expression	-90 to -240 (±5) mmHg	-40 to -245 (±5) mmHg	Different: The difference in vacuum range do not raise different questions of safety and effectiveness.
Cycle speed: stimulation	64 to 108 cycles/minute	70 to 114 cycles/minute	Different: The difference in cycle speed do not raise different questions of safety and effectiveness.
Cycle speed: Expression	26 to 48 cycles/minute	23 to 90 cycles/minute	Different: The difference in cycle speed do not raise different questions of

Item	Subject Device	Predicate Device (K212180)	Comparison
			safety and effectiveness.
Power supply	Li-Ion Battery	Li-Ion Battery	same
Indicators	Yes, LED	Yes, LED	same
Back flow protection	Yes	Yes	same
Materials	Valve: Silicone Breast shield, bottle, suction cap: Polypropylene	Milk Container: Polypropylene Flange: Silicone Pump Outer Housing: Acrylonitrile Butadiene Styrene (ABS) plastic	Similar

The indications for use of the subject and predicate devices are identical and they have the same intended use (i.e., the collection of breast milk from the breasts of lactating women).

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

VII Non-Clinical Testing

Non-clinical tests were conducted to verify that the subject device met all design specifications to be considered substantially equivalent to the predicate device.

Electrical Safety

- IEC 60601-1:2005+AMD 1:2012+AMD2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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

- IEC 60601-1-2:2014+AMD1:2020, Medical electrical equipment - Part 1-2: General

requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Biocompatibility Evaluation

Per the 2022 FDA guidance document “Use of international Standard ISO 10993-1, Biological evaluation of medical - Part 1: Evaluation and testing within a risk management process,” the following tests performed on the material which contacts with human for Biocompatibility:

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

Software

Software was evaluated as recommended in the 2005 FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

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.

IX Conclusion

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