June 6, 2024

Ningbo Dearevery Electronic Technology Co., LTD
Kelong Zhang
General Manager
No3-1, Gongji South Road, Hudi Village, Linshan Town
Yuyao, Zhejiang 315460
CHINA

Re: K232774
Trade/Device Name: Wearable Breast Pump, Model S18
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 5, 2024
Received: May 6, 2024

Dear Kelong Zhang:

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, PhD,
Assistant Director
DHT3B: Division of Reproductive,
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OHT3: Office of Gastrorenal, ObGyn,
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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)*
K232774

Device Name
Wearable Breast Pump, Model S18

Indications for Use *(Describe)*
The Wearable Breast Pump, Model S18 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.

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

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510(k) Summary – K232774

1. Submitter Information:

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2. Contact Person:

Kelong Zhang(General Manager)

3. Date prepared:

June 5, 2024

4. Device Information:

Device Name: Wearable Breast Pump, Model S18
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: Electric breast pump, model RH338
Manufacturer: Cixi Ruihong Electric Appliance Co., Ltd.
510(k) Number: K201903.
The predicate device has not been subject to a design-related recall.

6. Device Description:

The Wearable Breast Pump, Model S18 is an electrically powered breast pump to be used in home environment by a single user. The device is provided non-sterile and can be re-used by a single user. The device is electrically powered by an internal rechargeable Li-ion battery. It can be charged using 5V DC adaptor and the device is designed to be not used during charging.

The device consists of the pump motor, milk collection parts, adjustment buckle and charging cable. The device functionality is controlled using an embedded firmware. The subject device has three modes of operation - Expression mode, Stimulation mode and Massage mode, and each mode of operation allows for switching between nine suction levels.

The device has three buttons, a power button to turn the device on/off or switch between the modes, a '+ plus' button to increase the suction level and a '- minus' to decrease the suction level within a mode. The device includes an LED status display for the device operating mode and battery status indicator on the pump body. The operating mode LED changes to specific color based on the mode of operation. The device is designed to automatically shut down after 30 minutes of continuous operation.

The device operates on a suction(vacuum) cycle that consists of an inhale (letting in air to release vacuum) and an exhaust (removal of air to create vacuum) process. When the breast pump is powered on, the vacuum pump exhausts the air inside the cavity. Once the suction strength reaches the set value, the vacuum pump stops and the valve for the milk opens and expressed milk flows into the bottle due to a pressure difference.

All milk contacting components of the device are compliant with 21 CFR 177.

7. Indications for Use: The Wearable Breast Pump, Model S18 is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.

8. Predicate Device Comparison

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

Table 1 Comparison Between the Subject and Predicate Device

	Subject Device Wearable Breast Pump, Model S18 K232774	**Predicate Device Electric Breast Pump, Model RH-338 K201903**	Comment
Product Code	HGX (pump, breast, powered)	HGX (pump, breast, powered)	Same
Regulation Number	21CFR 884.5160, Powered breast pump	21CFR 884.5160, Powered breast pump	Same
Class	Class II	Class II	Same
Indication for Use	The Wearable Breast Pump, model S18 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 RH-338 and RH-228 electric breast pump is intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.	Similar
Single/double pumping	Single	Single	Same
Media Separation (backflow protection)	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Patient population	Lactating women	Lactating women	Same
Suction modes	3 modes - Massage mode, Stimulate mode, Expression mode	3 modes - Massage mode, Stimulate mode, Expression mode	Same
Suction Levels	9 levels, in each mode	9 levels, in each mode	Same
Vacuum strength (mmHg)	Massage mode: 101-165 Stimulate mode:108-180 Expression mode: 166-270	Massage mode: 135-255 Stimulate mode: 45-165 Expression mode: 110-300	**Different**
Cycle frequency (Cycles per minute)	Massage mode: 40-72 Stimulation mode: 24-40 Expression mode: 31-47	Massage mode: 56-72 Stimulate mode: 115-155 Expression mode: 25-52	**Different**
Battery indication	Yes	Yes	Same
Pump Type	Diaphragm	Diaphragm	Same
Power Supply	Li-ion battery	Li-ion battery and USB	**Different**
User Interface	Power button, mode button, Gear plus button, Gear minus button	On/Off button, Increase/decrease vacuum button, Switch mode button;	Similar
Maximum Suction	283.5 mmHg	300 mmHg	**Different**

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

The subject and predicate devices have similar technological features including suction modes and levels, pump type, user interface etc. The differences between the subject and predicate device include suction

strength, cycle frequency and power source. These differences do not raise new questions of safety and effectiveness and these differences in technological characteristics may be evaluated through performance testing.

9. Summary of Non-Clinical Performance Testing:

Biocompatibility Testing

The biocompatibility evaluation for the Wearable Breast Pump was conducted in accordance with 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."*. The tissue-contacting components were evaluated for cytotoxicity, irritation and sensitization and were found to be non-cytotoxic, non-irritating, and non-sensitizing.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Wearable Breast Pump device per the following standards:

- IEC 60601-1:2005+A1:2012+A2:2020, *Medical electrical equipment-Part 1: General requirements for basic safety, and essential performance*.
- IEC 60601-1-11:2015 +A1:2020, *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*.
- IEC 60601-1-2:2014+A1:2020, *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 +A1:2021, *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 & validation was provided in accordance with 2023 FDA guidance: *Content of Premarket Submissions for Device Software Functions*. The documentation level for the subject device is Basic Documentation Level.

Performance Testing and Use Life Verification

The subject device has a use-life of 3-years. The following performance testing were conducted at time T=0 and after fatigue testing equivalent to 3-years of device use to demonstrate that the device meets its performance specifications throughout its proposed use-life:

- Vacuum level and cycle frequency testing was performed for all modes and levels of operation to confirm that the device meets specifications for each mode and level.
- Backflow testing was conducted to verify that the fluid does not flow back into the tubing and to the pump.
- Battery capacity and service time testing was conducted to demonstrate that the battery meets its specified service time and the LED on the device accurately displays the battery charge status. The battery was also tested for its charging time.
- The button performance test was conducted to verify that the buttons maintain their functionality over proposed use-life of the device.
- Automatic shutdown function testing was conducted to demonstrate that the device shuts down automatically after 30 minutes of continuous operation.

10. Conclusion:

The results of the performance testing described above demonstrate that the Wearable Electric Breast

Pump, Model S18 is as safe and effective as the predicate device and supports a determination of substantial equivalence.