February 11, 2022

Shantou Huihengqi Electronic Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, Shanghai 200120
China

Re: K211024
Trade/Device Name: Electric Breast Pump (Models 918, HF918)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: January 8, 2022
Received: January 11, 2022

Dear Diana Hong:

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,

for
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)*
K211024

Device Name
Electric Breast Pump (Models 918, HF918)

Indications for Use *(Describe)*
The Electric Breast Pump (Models 918, HF918) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Electric Breast Pump 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

K211024

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR 807.92.

1. Date of 510(k) Summary Preparation: February 10, 2022

2. Sponsor Identification

Shantou Huihenggi Electronic Technology Co., Ltd.
501, 5/F, Block C, 14A Industrial Zone, Longhu District, Shantou, 515000, China

Establishment Registration Number: Not registered

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Tingting Su (Alternative Contact Person)

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Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Subject Device

Trade Name: Electric Breast Pump (Models 918, HF918)
Common Name: Electric Breast Pump
Models: 918, HF918

Regulatory Information
Classification Name: Powered Breast Pump
Product Code: HGX;
Classification: II
Regulation Number: 21 CFR 884.5160

5. Identification of Predicate device

510(k) Number: K201903
Product Name: Electric breast pump (Models: RH-228 and RH-338)

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

6. Device Description:

The Electric Breast Pump (Model 918 and HF918) are powered breast pumps intended to express and collect milk from a lactating woman's breast. Pumping can be performed on one breast (single pumping) or both breasts (double pumping) at the same time. The Electric Breast Pump is provided non-sterile and should be cleaned and disinfected according to the instructions for use prior to first use. The user employs buttons on the pump unit to select the pumping mode and vacuum level.

The Electric Breast Pump has five basic modes: Stimulation mode, Expression mode, Two-in-one mode, Dual-Frequency mode, and Simulation mode. Stimulation mode has 5 suction levels (vacuum levels: 60-217.5 ± 20 mmHg; cycle speed: 39-123 ± 5 cycles/min), expression mode (vacuum levels: 105-285 ± 20 mmHg; cycle speed: 24-84 ± 5 cycles/min), dual-frequency mode (vacuum levels: 67.5-277.5 ± 20 mmHg; cycle speed: 39-85 ± 5 cycles/min), and two-in-one mode (vacuum levels: 75-285 ± 20 mmHg; cycle speed: 59-123 ± 5 cycles/min) have seven suction levels, and simulation mode (vacuum levels: 187.5 ± 20 mmHg; cycle speed: 14 ± 5 cycles/min) has one suction level. Stimulation mode is for massaging the breast to stimulate breast milk secretion. Expression mode is for pumping breast milk. Dual Frequency mode is for cycling between strong and weak pumping strengths. Two-in-One mode cycles between massaging for 5 cycles and expressing breast milk for 1 cycle. Simulation mode operates at a single suction level to stimulate milk secretion.

The subject devices are available in two models: 918 and HF918. The hands-free (HF) model (HF918) is designed to be placed inside a user's bra and connect to the external pump unit. The milk collection

cup is located on the breast. The HF model (HF918) includes breast shield assemblies, milk collection cups, single and double tubing sets, a bottle set, power adapter, and a pump unit. The non-HF model (918) includes a breast shield connected to a milk bottle. The non-HF model includes breast shield assemblies, bottles, bottle stands, single and double tubing sets, power adapter, and a pump unit.

The Electric Breast Pumps are intended for a single user.

7. Indication for Use:

The Electric Breast Pump (Models 918, HF918) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Electric Breast Pump is intended for a single user.

8. Comparison of Technological Characteristics

Table 1 General Comparison

ITEM	**Subject Device** **Electric Breast Pump (918, HF918)** **K211024**	**Predicate Device** **Electric Breast Pump (Models: RH-228, RH-338)** **K201903**
Product Code	HGX	HGX
Class	II	II
Regulation No.	21 CFR 884.5160	21 CFR 884.5160
Indication for Use	The Electric Breast Pump (Models 918, HF918) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Electric Breast Pump is intended for a single user.	The 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.
Patient Population	Breastfeeding women	Breastfeeding women
Anatomical Sites	Breast	Breast
Single User	Yes	Yes
Provided Non-sterile	Yes	Yes
Direct user contact	Yes	Yes
Re-usable	Yes	Yes

Table 2 Technological Comparison

ITEM	**Subject Device** **Electric Breast Pump (918, HF918)** **K211024**	**Predicate Device** **Electric Breast Pump (Models: RH-228, RH-338)** **K201903**

Pump Type		Diaphragm	Diaphragm
Pumping Options		Single and Double Pumping	Single Pumping
Visual Indicator		918 & HF918: LED	RH-228: LED RH-338: LCD
Backflow Protection		Yes	Yes
Suction strength	Stimulation mode	918 & HF918: 60-217.5	RH-228:60-150 RH-338: 45-165
	Expression mode	918 & HF918: 105-285	RH-228:120-275 RH-338: 110-300
	Two-in One mode	918 & HF918: 75-285	N/A
	Dual-frequency mode	918 & HF918: 67.5-277.5	N/A
	Simulation mode	918 & HF918:187.5	N/A
	Massage mode	N/A	RH-338: 135-255
Suction level	Stimulation mode	918 & HF918: 5 levels	RH-228: 5 levels RH-338: 9 levels
	Expression mode	918 & HF918: 7 levels	RH-228: 4 levels RH-338: 9 levels
	Two-in One mode	918 & HF918: 7 levels	N/A
	Dual-frequency mode	918 & HF918: 7 levels	N/A
	Simulation mode	918 & HF918: 1 level	N/A
	Massage mode	N/A	RH-338: 9 levels
Cycling Speed	Stimulation mode	918 & HF918: 39-123	RH-228: 58-90 RH-338: 115-155
	Expression mode	918&HF918: 24-84	RH-228: 28-52 RH-338: 25-52
	Two-in One mode	918 & HF918: 59-123	N/A
	Dual-frequency mode	918 & HF918: 39-85	N/A
	Simulation mode	918 & HF918: 14	N/A
	Massage mode	N/A	RH-338: 56-72
Power Source		3.7 V, Lithium ion battery	3.7 V, Lithium ion battery
User Control		On pump body	On pump body

The subject and predicate device have same indications for use statements, and the same intended use. They are both used to express and collect milk from a lactating woman's breast.

The differences between the subject devices and the predicate devices are pumping options, suction levels, suction strength, and cycle speed. These differences do not raise different questions of safety and effectiveness.

9. 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 and Electromagnetic Compatibility

- IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance.
- IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility
- IEC 60601-1-11:2010, AMD1:2013, 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 62133:2012, 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

Biocompatibility testing in accordance with the FDA guidance "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" dated September 4, 2020. Testing included the following assessments:

- Cytotoxicity per ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- Sensitization and Irritation per ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Software Verification

- Software verification in accordance with the FDA Guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” dated May 11, 2005.

Additionally, the following non-clinical tests were conducted:

Suction strength of subject devices was tested. All the test results complied with the design specifications of the subject device throughout the use life.

Backflow testing was conducted to ensure that even if the bottle is over-filled, no liquid will backflow into the tubing, and therefore no liquid can backflow into the pump motor. The test results showed that there was no backflow during the test.

Cycle speed of subject devices was tested. All the test results complied with the design specifications of the subject devices throughout the use life.

Battery performance testing was conducted to demonstrate that the battery remains functional during its stated 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 comparison and analysis above demonstrate that the Electric Breast Pump (Models 918, HF918) is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device