April 9, 2021

Cixi Ruihong Electric Appliance Co., Ltd.
Kelong Zhang
General Manager
No. 18, Xiamaojia Road, Shuangqingpu Village, Xinpu Town, Cixi
Ningbo, Zhejiang 315322
China

Re: K201903
Trade/Device Name: Electric breast pump (Models: RH-228 and RH-338)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 9, 2021
Received: March 8, 2021

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 (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,

Michael T. Bailey -S

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)*
K201903

Device Name
Electric breast pump (Models: RH-228 and RH-338)

Indications for Use *(Describe)*
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.

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

K201903

1. **Submitter Information**:

Name:	Cixi Ruihong Electric Appliance Co., Ltd.
Address:	No.18, Xiamaojia Road, Shuangqingpu Village, Xinpu Town, Cixi, Ningbo, 315322, Zhejiang, China
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Date 510(k) Summary Prepared: April 7, 2021

2. **Device Information**

Trade/Proprietary Name:	Electric breast pump (Models: RH-228 and RH-338)
Regulation Name:	Powered breast pump
Regulation Number:	21 CFR 884.5160
Common Name:	Powered breast pump
Product Code:	HGX (Pump, Breast, Powered)
Regulatory Class:	Class II
Review Panel:	Obstetrics/Gynecology

3. **Predicative Device**

510(k) Number:	K163136
Manufacturer:	Ningbo Youhe Electrical Appliance Technology Co., Ltd.
Device Name:	Youha electric breast pump (Model: YH-8006IV)
	The predicate device has not been subject to a design-related recall.

4. **Device Description:**

The Electric breast pump is a single-patient reusable device, intended to be used by lactating women to express and collect milk from their breasts. The device uses a diaphragm-type vacuum pump driven by a microprocessor. The microprocessor provides control over vacuum pressure and cycle speed.

The Electric breast pump has two models: RH-228 and RH-338. Model RH-228 is capable of single pumping and has two modes – stimulate mode and expression mode. The RH-228 user interface consists of a panel keypad and LED display in which the user switches between modes and controls the vacuum pressure. Model RH-338 is capable of single pumping and has three modes – stimulate mode, massage mode and expression mode. The RH-338 user interface consists of a panel keypad and LCD display in which the user switches between modes and controls the vacuum pressure.

The RH-228 is externally powered by 5Vdc USB. The RH-338 is internally powered by 3.7Vdc lithium battery or externally powered by 5Vdc USB. The external adapter also charges the battery.

Both models of the Electric breast pump are provided with a breast shield, cylinder cap, cylinder, valve, vacuum tubing, feeding bottle, and a nipple kit. Model RH-338 also includes a massage cushion and a dust cap. The user-contacting materials are limited to polypropylene (breast shield) and silicone (massage cushion).

5. Indications for Use

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.

6. Comparison of Intended Use and Technological Characteristics

The following table compares the subject device to the predicate device with respect to the indications for use and technological characteristics:

Characteristics	**Subject Device** **Electric breast pump** **K201903**	**Predicate Device** **Youha Electric Breast Pump** **ModelYH-8006IV** **K163136**
Indications for Use	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.	The Youha 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.
Single-user	Yes	Yes
Provided Non-sterile	Yes	Yes

Re-usable	Yes		Yes
Direct user contact	Yes		Yes
Patient population	Lactating women		Lactating women
Anatomical Sites	Breast		Breast
Suction strength (mmHg)	RH-228	Expression mode: 120-275	High expression mode:125-280 Massage mode: 50-190
		Stimulate mode: 60-150	
	RH-338	Massage mode: 135-255	
		Stimulate mode: 45-165	
		Expression mode: 110-300	
Suction Levels	RH-228	Expression mode: 4 levels	10 levels
		Stimulate mode: 5 levels	
	RH-338: 9 levels		
Cycle Speed (cycles/min)	RH-228	Expression mode: 28-52	High expression mode:32-57 Massage mode: 71-100
		Stimulate mode: 58-90	
	RH-338	Massage mode: 56-72	
		Stimulate mode: 115-155	
		Expression mode: 25-52	
Backflow protection	Yes		Yes
Single or Double pumping	Single pumping		Single Pumping
Visual Indicator	RH-228: LED RH-338: LCD		LCD
Pump Type	Diaphragm		Diaphragm

The subject and predicate device have identical indications for use statements. Therefore, they have the same intended use, i.e., for collection of breast milk from the breasts of a single user.

The subject and predicate device have different technological features, including the user interface, expression levels, suction strength, cycle speed, and power source. These technological differences do not raise different questions of safety or effectiveness.

7. Summary of Non-clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications and that the subject devices are substantially equivalent to the predicate device.

a. Electrical Safety and Electromagnetic Compatibility:
   - 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 with US deviations per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012.
   - 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, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility
   - 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

b. Biocompatibility:
   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 per ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

- Irritation per ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

The user-contacting materials were shown to be biocompatible.

c. Software Verification:
   - Software verification and validation in accordance with the FDA Guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005.

d. Performance testing:
   - Vacuum pressure and cycle rate testing was conducted at all settings for each device model and demonstrated that the devices met their specifications.
   - Backflow testing was conducted to demonstrate that liquid does not backflow into the tubing/pump.
   - 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 comparison and analysis above demonstrate that the Electric breast pump is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device.