



April 3, 2026

Cixi Ruihong Electric Appliance Co.,Ltd.  
% Garen Liu  
Consulting consultant  
Grzan medical technology (Shenzhen) Co., LTD.  
Room 103-108, 1st Floor, Block B, Building 2  
Bangkai Science and Tech Park, Guanguang Rd, Guangming Dist  
Shenzhen, 518107  
China

Re: K252744  
Trade/Device Name: Wearable Electric Breast Pump (RH 668, RH 708, RH 718, RH 728)  
Regulation Number: 21 CFR§ 884.5160  
Regulation Name: Powered Breast Pump  
Regulatory Class: II  
Product Code: HGX  
Dated: March 3, 2026  
Received: March 3, 2026

Dear Garen Liu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Reginald K. Avery -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

## Indications for Use

510(k) Number (if known)  
K252744

Device Name  
Wearable Electric Breast Pump (RH 668, RH 708, RH 718, RH 728)

Indications for Use (Describe)

The Wearable Electric Breast Pump is a powered breast pump 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)

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### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510k Summary – K252744

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

### 1. Information of Submitter and correspondent

#### Submitter's information

Submitter Name: Cixi Ruihong Electric Appliance Co., Ltd.

Submitter Address: No.18, Xiamaojia Road, Shuangqingpu Village, Xinpu Town, Cixi, Ningbo, 315322, Zhejiang, China.

Contact Person (including Title): Liu Feng (Quality Manager)

Tel: +86 13759593691

E-mail: 13759593691@139.com

Date of Preparation: April 3, 2026

#### Contact information

Contact Address: Grzan Medical Technology (Shenzhen) Co., Ltd.

Rm. 103 – 108, 1<sup>st</sup> floor, Block B, Bldg. 2,

Bangkai Science And Tech Park, Guangang Rd. Guangming Dist, Shenzhen, 518107, China.

Contact Person: Garen Liu

Tel: +86 13100734866

E-mail: garen@grzan.cn

### 2. Device Identification

Trade Name: Wearable Electric Breast Pump (RH 668, RH 708, RH 718, RH 728)

Common Name: Powered breast pump

Regulation Number: 21 CFR 884.5160

Regulation Name: Powered breast pump

Product Code: HGX (Pump, Breast, Powered)

Classification Panel: Obstetrics/Gynecology

Regulatory Class: Class II

### 3. Predicate Device Information

	Predicate Device
Sponsor	Cixi Ruihong Electric Appliance Co., Ltd.

<b>Device Name</b>	Electric breast pump (Models: RH-228 and RH-338)
<b>510(k) Number</b>	K201903

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

#### **4. Device Description**

The Wearable Electric Breast Pump is an electrically powered wearable single breast pump. A diaphragm-type vacuum pump driven by a microprocessor, the microprocessor provides control over vacuum pressure and cycle speed. The Wearable Electric Breast pump consists of motor pump, breast shield, silicone diaphragm, USB cable, valve, storage tank and breast pump bracket.

There are four models (Models RH 668, RH 708, RH 718, RH 728) with 3 modes (stimulate mode, mixed mode and expression mode)

- Model RH 668 has 9 working levels
- Model RH 708 has 5 working levels
- Model RH 718 has 5 working levels
- Model RH 728 has 5 working levels

The subject device operates as a single or double pumping system, one on each breast. The pump is provided non-sterile and reusable by a single user. The device is powered by rechargeable Li-ion battery (3.7V, 1200 mAh). The subject device is designed not to be used during charging.

There is a LED status display for the subject device, including working mode, vacuum level, and battery indicator, can be shown on the pump body. The user interface includes on/off switch, mode selection, and vacuum adjustment.

#### **5. Indications for Use**

The Wearable Electric Breast Pump is a powered breast pump 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 with the Predicate Device

Item	Subject device K252744	Predicate device K201903	Comment																			
Indications for Use	The Wearable Electric Breast Pump is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It 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.	Similar																			
Pump Type	Wearable	Hand-held	Different																			
Media separation (backflow protection)	Yes	Yes	Same																			
Cycling control mechanism	microprocessor	microprocessor	Same																			
Power supply	Lithium battery 3.7V, 1200mAh	RH-228: 5VDC, 1A (without battery) RH-338: Lithium battery 3.7V, 850mAh	Different																			
Suction strength (mmHg)	<table border="1"> <tbody> <tr> <td rowspan="3">RH 668</td> <td>Mixed mode: 180-260</td> </tr> <tr> <td>Stimulate mode: 90-190</td> </tr> <tr> <td>Expression mode: 170-260</td> </tr> <tr> <td rowspan="3">RH 708</td> <td>Mixed mode: 90-230</td> </tr> <tr> <td>Stimulate mode: 90-220</td> </tr> <tr> <td>Expression mode: 140-260</td> </tr> <tr> <td rowspan="3">RH 718</td> <td>Mixed mode: 90-230</td> </tr> <tr> <td>Stimulate mode: 90-220</td> </tr> <tr> <td>Expression mode: 160-270</td> </tr> </tbody> </table>	RH 668	Mixed mode: 180-260	Stimulate mode: 90-190	Expression mode: 170-260	RH 708	Mixed mode: 90-230	Stimulate mode: 90-220	Expression mode: 140-260	RH 718	Mixed mode: 90-230	Stimulate mode: 90-220	Expression mode: 160-270	<table border="1"> <tbody> <tr> <td rowspan="2">RH 228</td> <td>Expression mode: 120-275</td> </tr> <tr> <td>Stimulate mode: 60-150</td> </tr> <tr> <td rowspan="3">RH 338</td> <td>Massage mode: 135-255</td> </tr> <tr> <td>Stimulate mode: 45-165</td> </tr> <tr> <td>Expression mode: 110-300</td> </tr> </tbody> </table>	RH 228	Expression mode: 120-275	Stimulate mode: 60-150	RH 338	Massage mode: 135-255	Stimulate mode: 45-165	Expression mode: 110-300	Different
RH 668	Mixed mode: 180-260																					
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	Stimulate mode: 60-150																					
RH 338	Massage mode: 135-255																					
	Stimulate mode: 45-165																					
	Expression mode: 110-300																					

	<b>RH 728</b>	<b>Mixed mode: 160-240</b>		
		<b>Stimulate mode: 100-220</b>		
		<b>Expression mode: 160-270</b>		

<p>Cycle Speed (cycles/min)</p>	<p><b>RH 668</b></p>	<p><b>Mixed mode: 48-60</b></p> <hr/> <p><b>Stimulate mode: 65-170</b></p> <hr/> <p><b>Expression mode: 23-76</b></p>	<table border="1"> <tr> <td data-bbox="858 461 975 611"> <p>RH 228</p> </td> <td data-bbox="975 461 1265 611"> <p>Expression mode: 28-52</p> <hr/> <p>Stimulate mode: 58-90</p> </td> </tr> <tr> <td data-bbox="858 611 975 837"> <p>RH 338</p> </td> <td data-bbox="975 611 1265 837"> <p>Massage mode: 56-72</p> <hr/> <p>Stimulate mode: 115-155</p> <hr/> <p>Expression mode: 25-52</p> </td> </tr> </table>	<p>RH 228</p>	<p>Expression mode: 28-52</p> <hr/> <p>Stimulate mode: 58-90</p>	<p>RH 338</p>	<p>Massage mode: 56-72</p> <hr/> <p>Stimulate mode: 115-155</p> <hr/> <p>Expression mode: 25-52</p>	<p><b>Different</b></p>
<p>RH 228</p>	<p>Expression mode: 28-52</p> <hr/> <p>Stimulate mode: 58-90</p>							
<p>RH 338</p>	<p>Massage mode: 56-72</p> <hr/> <p>Stimulate mode: 115-155</p> <hr/> <p>Expression mode: 25-52</p>							
<p>Modes</p>	<p><b>RH 668:</b>  <b>Mixed mode: 9 levels,</b>  <b>Stimulate mode: 9 levels,</b>  <b>Expression mode: 9 levels.</b></p> <p><b>RH 708:</b>  <b>Mixed mode: 5 levels,</b>  <b>Stimulate mode: 5 levels,</b>  <b>Expression mode: 5 levels.</b></p> <p><b>RH 718:</b>  <b>Mixed mode: 5 levels,</b>  <b>Stimulate mode: 5 levels,</b>  <b>Expression mode: 5 levels.</b></p> <p><b>RH 728:</b>  <b>Mixed mode: 5 levels,</b>  <b>Stimulate mode: 5 levels,</b>  <b>Expression mode: 5 levels.</b></p>	<p>RH 228:  Expression mode: 4 levels,  Stimulate mode: 5 levels.</p> <p>RH 338:  Massage mode: 9 levels,  Stimulate mode: 9 levels,  Expression mode: 9 levels.</p>	<p><b>Different</b></p>					



	<b>25.8 mm (for RH718)</b>		
Use-life	<b>2 years</b>	18 months	<b>Different</b>

In comparison to the predicate device, the subject device has the same intended use and similar indications for use statements.

As seen in the comparison table, the subject and predicate devices have different technological features, including pump type (wearable vs hand-held), power source, vacuum/cycle speed specifications, available suction levels, modes available, user interface, flange size, and use-life. These technological differences do not raise different questions of safety and effectiveness.

## 7. Summary of Non-clinical Performance Testing

A series of safety and performance tests were conducted on the subject device. All the test results demonstrate the Wearable Electric Breast Pump meets the requirements of its predefined acceptance criteria.

### Performance Verification

Bench performance testing was conducted to evaluate device performance:

-Vacuum pressure

-Cycle speed

-Backflow protection

-Battery capacity

-Operating time

-Charging time

### Use-Life Verification

Vacuum pressure, cycle speed and battery capacity were evaluated after conditioning equivalent to 2 years of use in the worst-case scenario.

### Biocompatibility testing

The biocompatibility evaluation for the Wearable Breast Pump was conducted in accordance with the 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,”” as follows:

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

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

### **Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted. The system complies with the following standards:

- 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.
- 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/A1:2021 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 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 and validation was conducted as recommended in the 2023 FDA guidance document, “Content of Premarket Submissions for Device Software Functions.” with a Basic Documentation Level.

### **8. Substantial Equivalence Conclusion:**

The results of the performance testing described above demonstrate that the Wearable Electric Breast Pump (RH 668, RH708, RH 718, RH728) is as safe and effective as the predicate device and supports a determination of substantial equivalence.