January 13, 2023

Zhejiang Carebao Co., Ltd.
Amos Zou
RA Engineer
3, No.1, Chuangye 4th Road, Ningbo Free Trade Zone
Ningbo, Zhejiang 325400
China

Re: K222782
Trade/Device Name: Wearable Breast Pump (Model:YD-1193,YD-1195,YD-1196,YD-1198,YD-1199;YD-1193S,YD-1195S,YD-1196S,YD-1198S,YD-1199S)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: December 15, 2022
Received: December 15, 2022

Dear Amos Zou:

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 and Part 809); 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,

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

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)*
K222782

Device Name
Wearable Breast Pump
(Model:YD-1193,YD-1195,YD-1196,YD-1198,YD-1199;YD-1193S,YD-1195S,YD-1196S,YD-1198S,YD-1199S)

Indications for Use *(Describe)*
The Wearable Breast Pump 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

1. Submitter of 510(K):

Sponsor：

Company Name:	ZHEJIANG CAREBAO CO., LTD.
Address:	3, No.1, Chuangye 4th Road, Ningbo Free Trade Zone, .Ningbo, Zhejiang, CN 325400
Contact person:	Mr. Yan Xie
TEL:	+86-574-87902421
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Application Correspondent:

Company Name:	ZHEJIANG CAREBAO CO., LTD.
Address:	3, No.1, Chuangye 4th Road, Ningbo Free Trade Zone, .Ningbo, Zhejiang, CN 325400
Contact person:	Mr. Amos Zou
TEL:	+86-15015249549
E-mail:	amos.zou@139.com

Date 510(k) Summary Prepared: January 12, 2023

2. Proposed Device and code:

Device Trade Name:	Wearable Breast Pump (Model:YD-1193,YD-1195,YD-1196,YD-1198,YD-1199; YD-1193S,YD-1195S,YD-1196S,YD-1198S,YD-1199S)
Product Code:	HGX (pump, breast, powered)
Common Name:	Powered breast pump
Regulation number	21 CFR 884.5160
Regulation Name	Powered breast pump
Regulatory Class	II

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K201903	Electric breast pump (Models: RH-338)	Cixi Ruihong Electric Appliance Co., Ltd.

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

4. Device Description:

The Wearable Breast Pump is an over-the-counter, non-sterile, single-user, powered breast pump intended to be used by lactating women to express and collect milk from their breasts. The device is intended for daily use in a home environment. The device uses a diaphragm-type vacuum pump driven by software embedded in the device. The software provides control over vacuum pressure and cycle speed.

The Wearable Breast Pump series includes ten models: YD-1193,YD-1195, YD-1196,YD-1198,YD-1199;YD-1193S,YD-1195S, YD-1196S,YD-1198S,YD-1199S. All model have a single pumping configuration only and operate in three modes – stimulation, expression, and mixed modes. The Wearable Breast Pump is capable of providing vacuum levels up to 290 mmHg. All modes include 9 vacuum user-selected levels.

Models YD-1195, YD-1198, YD-1199, YD-1193S, YD-1195S, YD-1196S, YD-1198S and YD-1199S are identical to model YD-1196 except for enclosure color and model name. YD-1196 and YD-1193 have the same suction modes, maximum vacuum, overvoltage protection function, button functions, backflow protection functions, and material composition, but are different in user interface, schematic circuit, appearance and construction. YD-1193,YD-1195, YD-1196,YD-1198,YD-1199 are retailed with one unit per package. YD-1193S,YD-1195S, YD-1196S,YD-1198S,YD-1199S are retailed with two units per package.

The Wearable Breast Pumps are designed to work under the user's bra and has a rechargeable 3.7V, 1100mAh lithium ion battery so it can be used hands-free without any external power cords. The subject device is charged from an external USB adapter and does not function when charging. The subject device consists of the following key components: the pump unit, connector body, silicone shield, dust cap, top cover, diaphragm, valve, airway tube, bottle, nipple, bottle cap set, bottle stand, and USB cable. The pump unit includes a press-button user interface, pump body, and LED display. The user interface includes user-adjustable controls for turning the device on/off, switching between massage mode and expression mode and mixed mode, and controlling vacuum level within each of the modes. The subject device expresses milk by creating a seal around the nipple using the flange and applying and releasing suction to the nipple. The milk is collected in a milk collection container. To prevent milk from flowing into the vacuum system, a backflow protection diaphragm physically separates the milk-contacting pathway from the vacuum system.

5. Indications for Use

The Wearable Breast Pump is intended to express milk from lactating women in order to collect milk from their breasts. The device 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:

	Subject Device	**Subject Device**	**Predicate Device**
510(k) No.	**K222782**	**K222782**	**K201903**
Product Name and model	Wearable Breast Pump (Model:YD-1193,YD -1193S, YD-1195,YD-1195S)	Wearable Breast Pump (YD-1196,YD-1198,YD-1199; YD-1196S,YD-1198S,YD-1199S)	Electric breast pump (Models: RH-338)
Product Code	HGX	HGX	HGX
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	21 CFR 884.5160
Regulatory Class	Class II	Class II	Class II
Single-user	Yes	Yes	Yes
Patient Population	Lactating Women	Lactating Women	Lactating Women
Indications for Use	The Wearable Breast Pump 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 Wearable Breast Pump 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 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.
Pump Options	Single	Single	Single
Provided Non-sterile	Yes	Yes	Yes
Re-usable	Yes	Yes	Yes
Direct user contact	Yes	Yes	Yes
Backflow Protection	Yes	Yes	Yes
Suction Modes	Stimulation Mode and Expression Mode Mixed Mode	Stimulation Mode and Expression Mode Mixed Mode	Stimulation Mode and Expression Mode Massage Mode

	Subject Device	**Subject Device**	**Predicate Device**
510(k) No.	**K222782**	**K222782**	**K201903**
Suction levels	9	9	9
Adjustable suction levels	Yes	Yes	Yes
Vacuum range -Stimulation mode	36 mmHg to 241 mmHg	37 mmHg to 242 mmHg	45 to 165 mmHg
Vacuum range: -Expression mode	69 mmHg to 282 mmHg	71 mmHg to 282 mmHg	110 to 300 mmHg
Vacuum range -Mixed mode	68mmHg to 280mmHg	68mmHg to 280mmHg	None
Cycle Speed -Stimulation mode	37.5 to 150 cycles/minute	37.5 to 150 cycles/minute	115-155 cycles/minute
Cycle Speed: Expression mode	23 to 72 cycles/minute	24 to 69 cycles/minute	25-52 cycles/minute
Cycle Speed -Mixed mode	12 to 21 cycles/minute	12 to 21 cycles/minute	None
Controls	On/Off button; Mode selection Increase/decrease vacuum button;	On/Off button; Mode selection Increase/decrease vacuum button;	On/Off button; Increase/decrease vacuum button

	Subject Device	**Subject Device**	**Predicate Device**
510(k) No.	**K222782**	**K222782**	**K201903**
Power Supply	Li-Ion Battery (internally powered by 3.7Vdc lithium battery or externally powered by 5Vdc USB.)	Li-Ion Battery (internally powered by 3.7Vdc lithium battery or externally powered by 5Vdc USB.)	Li-Ion Battery(internally powered by 3.7Vdc lithium battery or externally powered by 5Vdc USB.)
Indicators	Yes, LED	Yes, LED	Yes, LCD
Pump type	Diaphragm	Diaphragm	Diaphragm
Materials	Milk Container: Polypropylene Flange: Silicone Pump Outer Housing: Acrylonitrile Butadiene Styrene (ABS) plastic	Milk Container: Polypropylene Flange: Silicone Pump Outer Housing: Acrylonitrile Butadiene Styrene (ABS) plastic	Milk Container: Co-polymer polypropylene and silicone Flange: Polypropylene (grade changed) and silicone Pump Outer Housing: Polycarbonate and Thermoplastic polyurethane

The electric breast pump has the same intended use as the predicate device – to express and collect milk from lactating women. The subject and predicate device have different technological characteristics, including different suction modes, suction strengths, cycle speeds, and power source specifications. However, the differences in technological characteristics do not raise different questions of safety and effectiveness.

7. PERFORMANCE DATA

The testing for Wearable Breast Pump included use life testing, software, electrical safety, electromagnetic compatibility, biocompatibility and bench testing. Wearable Breast Pump passed all testing in support of the substantial equivalence determination:

7.1. Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*. As dictated by the nature of body contact (intact skin) and contact duration (less than 24 hours), the following endpoints were evaluated for the patient-contacting components:

1) Cytotoxicity per ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

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

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

The results of these test demonstrated that the patient-contacting components of the subject device are non-cytotoxic, non-sensitizing, and non-irritating.

7.2. Electrical safety and electromagnetic compatibility

The subject device has been tested in accordance with and found to comply with the following standards:

1) ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

2) IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

3) ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021] Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)]

4) IEC 62133-2:2017, 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 – Part 2: Lithium systems, and found to comply with all relevant sections.

7.3. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

7.4. Sterilization, Cleaning, and Shelf-Life

Sterilization and Cleaning

The device is reusable, provided non-sterile, and is not sterile when used. Cleaning instructions are provided in the labeling.

Shelf-Life

Shelf-life is not applicable due to the low likelihood of time-dependent product degradation. However, in accordance with IEC 60601-1:2005/(R)2012 the subject devices expected use-life is 1500 pumping sessions of 30 minutes per session. In testing, the devices were demonstrated to operate within specifications for up to

1,500 pumping sessions including at the maximum setting (Expression Mode, Level 9).

7.5. Performance Testing

1) Vacuum performance testing, cycle performance testing, and backflow protection testing was conducted at minimum and maximum vacuum settings to determine the minimum and maximum vacuum levels of the pump as compared to its specifications. The specifications were met for vacuum level, cycle rate, and backflow protection. These results held under conditions of single pumping mode under battery power.

2) Use life testing was conducted to demonstrate that the device maintains its performance specifications throughout its proposed use-life

3) Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life

4) Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.

8. Conclusions:

The results of the 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.