December 1, 2021

Zhejiang Carebao Co., Ltd.
% Iris Wang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square,
Liuxian Avenue Xili Town
Shenzhen, Guangdong 518000
CHINA

Re: K211755
Trade/Device Name: Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: October 15, 2021
Received: November 1, 2021

Dear Iris Wang:

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,

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)*
K211755

Device Name
Electric Breast Pump

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.

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

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510(k) Summary – K211755

1. Submitter Information

Prepared Date	November 30, 2021
Manufacturer	Zhejiang Carebao Co., Ltd. Address: 3, No.1, Chuangye 4th Road, Ningbo Free Trade Zone, Ningbo, Zhejiang, China. Contact person: Yan Xie TEL: +86-574-87902421 E-Mail: xie.yan@unibono.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China. Contact person: Mr. Field Fu; Ms. Iris Wang; E-Mail: field@cefda.com; iris@cefda.com

2. Device Information

Type of 510(k):	Traditional
510(k) Number:	K211755
Device Name/Trade Name:	Electric Breast Pump
Common Name:	Powered breast pump
Model:	YD-1130S, YD-1132S, YD-1168
Regulation Name:	Powered breast pump
Regulation Number:	884.5160
Product Code:	HGX (Pump, Breast, Powered)
Regulatory Class:	II

3. Predicate Device Information

Manufacturer:	Shenzhen Bosidin Technology Co. Ltd.
Device Name:	Youha electric breast pump
Model:	YH-8004, YH-8016, YH-8006IV, YH-8015
510(k) Number:	K163136
Product Code:	HGX

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

4. Device Description

The electric breast pump is an over-the-counter 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 by a single user.

The electric breast pump includes three models: YD-1130S, YD-1132S, and YD-1168. YD-1130S and YD-1132S has a double pumping (pumping from both breasts at the same time) configuration only. YD-1168 has both single pumping (pumping from one breast) and double pumping (pumping from both breasts at the same time) configurations.

The electric breast pump is comprised of the pump unit, system parts (including connector body, silicone shield, dust cap, top cover, diaphragm, valve, airway tube, bottle, nipple, bottle cap set, bottle stand), and USB cable.

The electric breast pump provides the following features:

1) Models YD-1130S and YD-1168 have two suction modes, as listed below:
    - Massage mode: Suction patterns with fast cycles and low vacuum to start milk flowing.
        - Five vacuum levels from level L1-L5 for massage mode
    - Expression mode: Suction patterns with slower cycles and higher vacuum to express milk gently and efficiently.
        - Nine vacuum levels from level L1-L9 for expression mode.
2) Model YD-1132S has two suction as listed below:
    - Massage mode: Suction patterns with fast cycles and low vacuum to start milk flowing.
        - Six vacuum levels from level L1-L6 for massage mode
        - Vacuum level L6 of massage mode is called “Let-down control”, which operates as follows: Quickly suck 3 times to start milk flowing (massage mode) and then slowly suck 1 time (expression mode).
    - Expression mode: Suction patterns with slower cycles and higher vacuum pressure

to express milk gently and efficiently.

- Nine vacuum levels from level L1-L9 for expression mode

The electric breast pump has user-adjustable controls for turning the device on/off, switching between massage mode and expression mode, controlling vacuum level within each of the modes, and selecting between single pumping and double pumping modes (for model YD-1168 only). The electric breast pump is capable of providing a vacuum pressure up to 280 mmHg.

The device is electrically powered from either an internal rechargeable battery or an external AC power adapter. The external adapter also charges the battery. The Micro USB port of the pump unit is for connection of the AC power adapter through USB cable, and the AC power adapter is connected to AC mains for charging.

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 with Predicate Device

A comparison of the intended use and technological characteristics of the subject and predicate device is provided in the table below:

Items	Subject Device	Predicate Device (K163136)	Comparison
Device name and model	Electric Breast Pump, Models: YD-1130S, YD-1132S, YD-1168	Youha electric breast pump, Models: YH-8004, YH-8016	N/A
Product code	HGX	HGX	Same
Regulation number	884.5160	884.5160	Same
Device class	2	2	Same
Location for use	OTC	OTC	Same
Indications for use	The electric breast pump is intended to be used by lactating women to express	The Youha electric breast pump is intended to be used by lactating women to	Same

	and collect milk from their breasts. It is intended for a single user.	express and collect milk from their breasts. It is intended for a single user.	
Single user	Yes	Yes	Same
Provided non-sterile	Yes	Yes	Same
Re-usable	Yes	Yes	Same
Direct user contact	Yes	Yes	Same
Power source	Micro USB: 5V, 2A (supplied by an AC adapter with a USB port) or internal rechargeable battery	AC/DC wall converter and Rechargeable	Similar
Vacuum range (Massage mode)	YD-1130S: 34~190 mmHg	34-190 mmHg	Different
	YD-1132S: 34~280 mmHg		
	YD-1168: Single pumping: 34~190 mmHg Double pumping: 89~190 mmHg		
Vacuum range (expression mode)	YD-1130S: 67~280 mmHg	Low: 75-250mmHg High: 120-280mmHg	Different
	YD-1132S: 97~280 mmHg		
	YD-1168: Single pumping: 87~280 mmHg Double pumping: 96~280 mmHg		
Cycle speed (Massage mode)	YD-1130S: 40 ~140 cycles/min	94-113 cycles/minute	Different
	YD-1132S: 10~140 cycles/min		
	YD-1168: Single pumping: 52~140 cycles/min		

	Double pumping: 63~105 cycles/min		
Cycle speed (expression mode)	YD-1130S: 24~70 cycles/min	Low: 41-69 cycles/minute High: 16-33 cycles/minute	Different
	YD-1132S: 21~68 cycles/min		
	YD-1168: Single pumping: 25~78 cycles/min Double pumping: 28~83 cycles/min		
Adjustable suction levels	Yes	Yes	Same
Suction settings (Massage mode)	YD-1130S: 5	6	Different
	YD-1132S: 6		
	YD-1168: 5		
Suction settings (expression mode)	YD-1130S: 9	6	Different
	YD-1132S: 9		
	YD-1168: 9		
Overflow protection	Yes	Yes	Same
Pumping options	YD-1130S/YD-1132S: Double pumping	Single and double pumping	Similar
	YD-1168: Single or Double pumping		
Visual indicator	LED indicators	LCD	Different
Pump type	Diaphragm	Diaphragm	Same

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 pumping options, modes, suction levels, suction strengths, cycle speeds, visual indicator, and power source. However, the differences in technological characteristics do not raise different questions of safety and effectiveness.

7. Non-Clinical Test Summary

Non-clinical tests were conducted to verify that the proposed device met all design specifications and that the subject device is substantially equivalent to the predicate device, as follows:

7.1. Electromagnetic Compatibility and Electrical Safety

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 and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2) IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3) 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

7.2. 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:

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.

7.3. 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 and double pumping mode with varying power sources (i.e., AC adapter power and 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

7.4. Software

The software documentation of the subject device was provided in accordance with FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued May 11, 2005.

8. Conclusion

The results of the testing described above demonstrate that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.