July 8, 2021

Ningbo Youhe Electrical Appliance Technology Co., Ltd.
% Daniel Qiu
Project Manager
Shanghai Qisheng Business Consulting Co., Ltd.
Room 1301, Bld. 46, Jing Gu Zhong Rd. No. 58, Min Hang District
Shanghai, Shanghai 200240
China

Re: K203148
Trade/Device Name: Youha Electric Breast Pump (Models: THE ONE, YH-8011, YH-8012, YH-8019, YY-5030)
Bebebao Electric Breast Pump (Model: BB-5020)
Yiyadodo Electric Breast Pump (Model: YY-5030)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: June 8, 2021
Received: June 8, 2021

Dear Daniel Qiu:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203148

Device Name
Youha Electric Breast Pump (Models: THE ONE, YH-8011, YH-8012, YH-8019, YY-5030)
Bebebao Electric Breast Pump (Model: BB-5020)
Yiyadodo Electric Breast Pump (Model: YY-5030)

Indications for Use *(Describe)*
The electric breast pumps are intended to be used by lactating women to express and collect milk from their breasts. They are intended for a single user. The electric breast pumps are intended for at home use.

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

I. Submitter Information

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Project Manager

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Fax: +86-21-58748429

II. Date Prepared: July 6, 2021

III. Device Information

Trade name: Youha Electric Breast Pump (Models: THE ONE, YH-8011, YH-8012, YH-8019, YY-5030)
Bebebao Electric Breast Pump (Model: BB-5020)
Yiyadodo Electric Breast Pump (Model: YY-5030)

Common name: Powered breast pump

Regulation class: Class II

Regulation number: 21 CFR 884.5160

Regulation name: Powered breast pump

Product code: HGX (pump, breast, powered)

IV. Predicative Device

510(k): K163136

Device name: Youha Electric breast pump

Manufacturer: NINGBO YOUHE ELECTRICAL APPLIANCE TECHNOLOGY CO., LTD.

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

V. Device Description

The Youha, Bebebao, and Yiyadodo electric breast pumps are single-user, powered breast pump intended to be used by lactating women to express and collect milk from their breasts. THE ONE, YH-8012, BB-5020 and YY-5030 have both single (pumping from one breast) and double pumping (pumping from both breasts) configurations. YY-8011 and YH-8019 have a single pumping configuration only.

A reciprocating diaphragm vacuum pump, driven by a microprocessor, generates the suction to extract the milk at vacuum levels up to 280 mmHg. The user interface for the THE ONE, YH-8012, BB-5020 and YY-5030 models consists of a front panel keypad and LCD display or LED display in which the user switches between modes and controls the vacuum pressure. The YY-5030 model does not have any visual indicators on the pump housing.

The device has three modes of operation:

- Massage mode: Suction patterns with fast cycles and low vacuum to start milk flowing
- Low expression mode: Suction patterns with slow cycles and high vacuum to express more milk gently and efficiently.
- High expression mode: Suction patterns with slower cycles and higher vacuum to express more milk efficiently.

THE ONE, YH-8012 and BB-5020 have 3 modes including massage mode, low expression mode and high expression mode. YY-5030, YH-8011, and YH-8019 have 2 modes including massage mode and high expression mode.

The device is electrically powered from either an internal lithium ion rechargeable battery or an external AC power adapter. The external adapter also charges the battery.

VI. Indication for Use

The electric breast pumps are intended to be used by lactating women to express and collect milk from their breasts. They are intended for a single user. The electric breast pumps are intended for at home use.

VII. Predicate Comparison

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

<table>
<tr><th></th><th colspan="2">Subject device
Youha Electric Breast Pump
Bebebao Electric Breast Pump
Yiyadodo Electric Breast Pump
K203148</th><th colspan="2">Predicate device
Youha Electric breast pump
K163136</th></tr>
<tr><td>Indication for Use</td><td colspan="2">The electric breast pumps are intended to be used by lactating women to express and collect milk from their breasts. They are intended for a single user. The electric breast pumps are intended for at home use.</td><td colspan="2">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.</td></tr>
<tr><td>Single user</td><td colspan="2">Yes</td><td colspan="2">Yes</td></tr>
<tr><td>Provided Non-sterile</td><td colspan="2">Yes</td><td colspan="2">Yes</td></tr>
<tr><td>Re-usable</td><td colspan="2">Yes</td><td colspan="2">Yes</td></tr>
<tr><td>Direct user contact</td><td colspan="2">Yes</td><td colspan="2">Yes</td></tr>
<tr><td>Power source</td><td colspan="2">AC/DC wall converter and Rechargeable Lithium-Ion battery</td><td colspan="2">AC/DC wall converter and Rechargeable Lithium-Ion battery</td></tr>
<tr><td rowspan="2">Suction Strength (Expression Mode) (mmHg)</td><td>Low</td><td>THE ONE:75-250
YH-8012:75-250
BB-5020:75-250</td><td>Low</td><td>YH-8004:75-250
YH-8016:75-250
YH-8015:115-250
YH-8006IV:N/A</td></tr>
<tr><td>High</td><td>THE ONE:110-280
YH-8012:110-280
YY-5030: 110-280
YH-8011:120-280
BB-5020:110-280
YH-8019:120-280</td><td>High</td><td>YH-8004:120-280
YH-8016:120-280
YH-8015: 120-280
YH-8006IV:125-280</td></tr>
<tr><td>Suction Strength (Massage Mode) (mmHg)</td><td colspan="2">THE ONE:35-190
YH-8012:35-190
YY-5030:35-190
YH-8011:50-190
BB-5020:35-190
YH-8019:50-190</td><td colspan="2">YH-8004:34-190
YH-8016:34-190
YH-8015: 50-190
YH-8006IV: 50-190</td></tr>
<tr><td>Adjustable suction levels</td><td colspan="2">Yes</td><td colspan="2">Yes</td></tr>
<tr><td rowspan="6">Suction Settings (High/low Expression Mode)</td><td colspan="2">THE ONE:6</td><td colspan="2" rowspan="6">YH-8004:6
YH-8016:6
YH-8015:9
YH-8006IV:10</td></tr>
<tr><td colspan="2">YH-8012:9</td></tr>
<tr><td colspan="2">YY-5030:9</td></tr>
<tr><td colspan="2">YH-8011:9</td></tr>
<tr><td colspan="2">BB-5020:9</td></tr>
<tr><td colspan="2">YH-8019:9</td></tr>
</table>

	Subject device Youha Electric Breast Pump Bebebao Electric Breast Pump Yiyadodo Electric Breast Pump K203148		Predicate device Youha Electric breast pump K163136	
Suction Settings (Massage Mode)	THE ONE:6 YH-8012:9 YY-5030:9 YH-8011:9 BB-5020:9 YH-8019:9		YH-8004:6 YH-8016:6 YH-8015:9 YH-8006IV:10	
Cycle Speed (Expression Mode) (cycles/min)	Low	THE ONE:41-69 YH-8012:39-77 BB-5020:39-77	Low	YH-8004:41-69 YH-8016:41-69 YH-8015:36-60 YH-8006IV:N/A
	High	THE ONE:16-34 YH-8012:16-35 YY-5030:26-54 YH-8011:30-57 BB-5020:16-35 YH-8019:30-58	High	YH-8004: 16-33 YH-8016:16-33 YH-8015: 16-34 YH-8006IV:32-57
Cycle Speed (Massage Mode) (cycles/min)	THE ONE:93-115 YH-8012:84-115 YY-5030:58-115 YH-8011:67-100 BB-5020:84-115 YH-8019:71-100		YH-8004:94-113 YH-8016:94-113 YH-8015:80-122 YH-8006IV:71-100	
Back Flow Protection	Yes		Yes	
Single or Double Pumping	THE ONE/ YH-8012/ YY-5030/ BB-5020: Single and Double pumping YY-8011/ YH-8019: Single pumping only		YH-8004/ YH-8016: Single and Double Pumping YH-8006IV/ YH-8015: Single Pumping Only	
Visual Indicator	LCD/LED (THE ONE, YH-8012, BB-5020, YY-8011, YH-8019) No visual indicator (YY-5030)		LCD	
Pump type	Diaphragm		Diaphragm	

The subject devices have the same intended use but different technological characteristics compared to the predicate device. The subject and predicate device operate at different cycle speeds, levels, and suction strengths for massage and expression modes. The subject device also has different visual indicators for the

pump user interface. The differences in technological characteristics do not raise different questions of safety and effectiveness.

VIII. Non-clinical Performance Testing

Non-clinical tests were conducted to verify that the electric breast pumps met all design specifications and is substantially equivalent to the predicate. The test results demonstrated that the proposed device complies with the following standards and guidance documents:

- Risk Analysis developed in accordance with ISO 14971:2007.
- Electrical Safety Testing in accordance with IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES 60601-1:2005/(R)2012 and Al:2012.
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014.
- Safety Testing for use in the home in accordance with IEC 60601-1-11:2015.
- Biocompatibility evaluation was completed according to the FDA guidance "Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," dated September 4, 2020, and concluded that no new testing was required as all patient-contacting materials are identical to those used in cleared Youha electric breast pumps (K163136).
- Software Validation - Software Life Cycle Processes in accordance with lEC 62304:2016.
- FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005).

Performance 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 for the duration of a pumping session, identified as 30 minutes. These specifications were maintained under conditions of single and double pumping mode with varying power sources (e.g., AC/DC power vs. battery power). Battery and pump use life testing were conducted to demonstrate the device maintains its specifications throughout its use life under varying power sources (AC, battery).

IX. Conclusion

The subject and predicate devices have the same intended use and the technological differences do not raise different questions of safety or effectiveness. The performance data demonstrate the subject device is substantially equivalent to the predicate device.