January 16, 2020

Ningbo Huiyoo Baby Products Co. Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O Box 120-119
Shanghai, 200120
CHINA

Re: K191802
Trade/Device Name: Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: December 19, 2019
Received: December 23, 2019

Dear Diana Hong:

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,

for Sharon M. Andrews
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)*
K191802

Device Name
Electric Breast Pump

Indications for Use *(Describe)*
The Electric Breast Pumps are intended to express and collect milk from the breast of a lactating woman.

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

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

The assigned 510(k) Number: K191802

1. Sponsor Identification

Ningbo Huiyoo Baby Products Co. Ltd.
523# Cizhang Road, Zhangqi Industrial Area, Cixi, 315313, Zhejiang, China

Contact Person: Xiaoping Liu
Position: Electrical Engineer
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Email: liuxiaoping@foxmail.com

2. Date of Preparation: January 15, 2020

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Electric Breast Pump;
Common Name: Breast Pump
Models: BLA8015-02

Regulatory Information
Classification Name: Pump, Breast, Powered;
Classification: II
Product Code: HGX;
Regulation Number: 21 CFR 884.5160;
Review Panel: Obstetrics/Gynecology;

5. Identification of Predicate Device

510(k) Number: K151284
Product Name: Electric Double Breast Pumps
Manufacturer: Wuxi Xinzhongrui Baby Supplies Co., Ltd.

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

6. Device Description

The Electric Breast Pump BLA8015-02 is designed and manufactured to express and collect milk from a lactating woman's breast. The subject device is electrically powered, software-controlled, digital single-user pumps.

The pump is available in 4 different modes, which are massage mode, continuous express mode, frequency conversion mode and normal express mode. The different modes can be distinguished by different keys displayed on the LCD. There are 6 expression levels for massage mode and continuous expression mode, and 9 expression levels for frequency conversion mode and normal expression mode. The suction strengths are different for different working modes. The suction strength can be adjusted within 20~240mmHg by the user. When powered, the subject device starts with massage mode at level 1. The mode switch and level adjustment can be achieved by mode keys.

A suction cycle consists of an inhale process and an exhaust process. When the breast pump is powered on, the vacuum pump exhausts the air inside the cavity. When the suction strength reaches the setting value, the vacuum pump stops working and the expressed milk opens the valve and then flows into the bottle due to pressure difference.

The pump is provided in non-sterile and can be re-used by a single user. The device has embedded software and the level of concern for the software is minor. The device is powered by Li-ion battery.

The patient contact component and milk contact component are massage cushion and milk bottle. The contact duration and contact level is limited skin contact. The massage cushion and milk bottle are respectively made of polypropylene and silicone gel. The materials meet the requirements of FDA regulations concerning food contact.

The device can be used in both hospital and home environment.

7. Indication for Use

The Electric Breast Pumps are intended to express and collect milk from the breast of a lactating woman.

Subject Device	Predicate Device
The Electric Breast Pumps are intended to express and collect milk from the breast of a lactating woman.	The powered Electric Double Breast Pumps are intended to express and collect milk from the breast of a lactating woman. They are double pumps with a single pumping option and intended for single user.

The indications for use of the subject device are similar to that of the predicate. The subject device is indicated for single pumping and for a single user, while the predicate is indicated for single and double pumping in a single user. The differences in the indications statements do not alter the intended use of the subject device as compared to the predicate.

8. Comparison of Technological Characteristics

Table 1 Comparison of Technological Characteristics

ITEM	Proposed Device	Predicate Device, K151284
Product Code	HGX	HGX
Regulation No.	21 CFR 884.5160	21 CFR 884.5160
Class	II	II
Indication for Use	The Electric Breast Pumps are intended to express and collect milk from the breast of a lactating woman.	The powered Electric Double Breast Pumps are intended to express and collect milk from the breast of a lactating woman. They are double pumps with a single

		pumping option and intended for single user.
Patient Population	Breastfeeding women	Breastfeeding women
Anatomical Sites	Breast	Breast
Pump Type	Reciprocating Diaphragm	Reciprocating Diaphragm
Pumping Options	Single	Single or Double
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor
Suction Levels	6 and 9	7 and 9
Suction Strength	20~240 mmHg	60 -240 mmHg
Cycle Speed	6.5~92.3 cycle/min	Single: 36 – 103 cycles / min Double: 25 – 76 cycles / min
Power Supply	3.7V 2200mAh Li-ion	6V DC Adaptor or batteries
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Back Flow Protection	Yes	Yes
Patient Contact Material	Silicone gel	Silicone gel
Biocompatibility	No cytotoxicity, irritation or sensitization	No cytotoxicity, irritation or sensitization

The differences between proposed device and predicate include suction levels, suction strength, cycle speed and power supply. These differences do not raise any question regarding its safety and effectiveness. The differences in technological characteristics may be evaluated through performance testing.

9. 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 device is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance.

IEC 60601-1-11:2010, 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

ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

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

The software was verified and validated. Software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, published on May 11, 2005 for a minor level of concern.

Additionally, the following non-clinical tests were conducted:

Vacuum pressure of proposed devices was tested. All the tests results complied with the design specifications of the proposed devices.

Backflow testing was conducted to ensure that even if the bottle is over-filled, no liquid will backflow into the tubing, and therefore no liquid can backflow into the pump motor. The test results showed that there was no backflow during the test.

10. Conclusion

The performance testing demonstrate that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate device.