August 26, 2021

Wuxi Xinzhongrui Baby Supplies Co., Ltd.
℅ Shelley Li
Manager
Shanghai Landlink Medical Information Technology Co., Ltd.
Room 703, 705, Building 1, West Guangzhong Road 555, Jingan District
Shanghai, 200071
China

Re: K202802
Trade/Device Name: TT Electric Breast Pump, TT Double Electric Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: August 11, 2021
Received: August 16, 2021

Dear Shelley Li:

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 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)*
K202802

Device Name
TT Electric Breast Pump, TT Double Electric Breast Pump

Indications for Use *(Describe)*
The TT Electric Breast Pump and TT Double Electric Breast Pump are intended to express and collect milk from the breast of a lactating woman. This powered breast pump is intended for a single user and is intended to be used in a home environment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 – K202802

1. Submitter Information

Applicant: Wuxi Xinzhongrui, Baby Supplies Co., Ltd.
Address: No. 117 Xinhua, Road, Meicun,
New Wu District, Wuxi,
Jiangsu, 214000, China.

2. Correspondent Information

Contact: Shelley Li
Manager, Regulatory Affairs
Phone: + 86 (021) 803-17636
Email: shelley.li@landlink-healthcare.com

3. Date prepared: August 24, 2021

4. Device Information

Device Name:	TT Electric Breast Pump TT Double Electric Breast Pump
Common Name:	Powered Breast Pump
Regulation Number:	21 CFR 884.5160
Regulation Name:	Powered Breast Pump
Product Code:	HGX (Pump, Breast, Powered)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Megna Breast Pumps (Models M5, M7, M10 and M12)
510(k) Number:	K142479
Manufacturer:	Wuxi Xinzhongrui, Baby Supplies Co., Ltd.
Product Code:	HGX (Pump, Breast, Powered)

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

6. Device Description

The TT Electric Breast Pump and TT Double Electric Breast Pump are intended to express and collect milk from the breast of a lactating woman. The devices are intended for a single user.

The subject devices are for repeated use by a single user and are for use in home and professional healthcare environments. The devices are not sterile.

The subject devices are electrically powered double (TT Double Electric Breast Pump) and single (TT Electric Breast Pump) breast pumps consisting of the following key components: a motor unit with a press-button user interface, pump body, LCD display, air tube connectors, and breast milk collection bottles. The motor unit operates on embedded software. Software updates by end-users are not supported.

The breast pump extracts milk from the breasts by creating a seal around the nipple and applying and releasing suction to the nipple. The milk is collected in a milk collection container, which can be used for storage. To prevent milk from flowing into the vacuum system, a protection membrane physically separates the milk-contacting pathway from the vacuum system.

The motor unit operates on a rechargeable battery or on an external mains adapter that is provided with the system via a micro-USB type connection. The rechargeable battery can be charged from the external mains adapter if the motor unit is not in operation.

All other components of the subject devices are not in contact with the breast.

Table 1: Subject Device variants

Trade/Device Name	Number of pumps	User Interface	Battery	Expression kit type
TT Electric Breast Pump, Model:1162	1	4 buttons and LCD display	With battery	Diaphragm
TT Electric Breast Pump, Model:1183	2	5 buttons and LCD display	With Battery	Diaphragm

The subject devices consist of the following materials:

- Motor unit: ABS, mABS, HTV Silicone
- Cushion, tube, milk valve, diaphragm: Silicone
- Pump body, milk collection container: Polypropylene
- Flange: Polypropylene, Polybutylene Terephthalate, Silicone

All milk contacting components are compliant with 21 CFR 174-179, 21 CFR 177.1520 and 21 CFR 177.2600.

7. Indications for Use

The TT Electric Breast Pump and TT Double Electric Breast Pump are intended to express and collect milk from the breast of a lactating woman. This powered breast pump is intended for a single user and is intended to be used in a home environment.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 2: Comparator Table for Subject and Predicate Devices

	TT Electric Breast Pump K202802 Subject Device	Megna Breast Pumps K142479 Predicate Device	Comparison
Product Name	TT Electric Breast Pump, TT Double Electric Breast Pump	Megna Models M5, M7, M10 and M12	
Product Code	HGX	HGX	**Same**
Regulation No.	21 CFR 884.5160	21 CFR 884.5160	**Same**
Class	Class II	Class II	**Same**
Patient Population	Lactating Women	Lactating Women	**Same**

Environment of use	Home Environment	Home Environment	**Same**
Indications for Use	The TT Electric Breast Pump and TT Double Electric Breast Pump are intended to express and collect milk from the breast of a lactating woman. This powered breast pump is intended for a single user and is intended to be used in a home environment.	The powered Megna Breast Pumps are intended to express and collect milk from the breast of a lactating woman. The M5 model is a single pump. The M7, M10, and M12 models are double pumps with a single pumping option. All models are intended for single users.	**Same**
Pump Options	Single or Double	Single or Double	**Same**
Backflow Protection	Yes	Yes	**Same**
Suction Modes	Stimulation Mode and Expression Mode	Stimulation Mode and Expression Mode	**Same**
Pump Type	Reciprocating Diaphragm	Reciprocating Diaphragm	**Same**
Transition between suction modes	Automatic or Manual	Manual	**Same**
Adjustable suction levels	Yes	Yes	**Same**
Vacuum range: Stimulation	1162: -75 to -300 mmHg 1183: -75 to -300 mmHg	M5 Single: -120 to -304 mmHg M7 Single & Double: -68 to -300 mmHg M10 Single: -60 to -297 mmHg M10 Double: -60 to -300 mmHg M12 Single: -60 to -297 mmHg M12 Double: -64 to -297 mmHg	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in maximum suction pressure were substantiated by performance testing below.
Vacuum range: Expression	1162: -105 to -300 mmHg 1183: -105 to -300 mmHg	M5 Single: -120 to -304 mmHg M7 Single & Double: -68 to -300 mmHg M10 Single: -60 to -297 mmHg M10 Double: -60 to -300 mmHg M12 Single: -60 to -297 mmHg M12 Double: -64 to -297 mmHg	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in maximum suction pressure were substantiated by performance testing below.
Cycle Speed: Stimulation	1162: 72 to 117 cycles/min 1183: 69 to 114 cycles/min	M5: 26 to 80 cycles/min M7: 15 to 68 cycles/min M10: 38 to 139 cycles/min M12: 13 to 48 cycles/min	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in cycle speed were substantiated by performance testing below.
Cycle Speed: Expression	1162: 23 to 86 cycles/min 1183: 24 to 92 cycles/min	M5: 26 to 80 cycles/min M7: 15 to 68 cycles/min M10: 38 to 139 cycles/min M12: 13 to 48 cycles/min	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in cycle speed were substantiated by performance testing

			below.
Controls	On/Off button; Increase/decrease vacuum button; Switch mode button; (1183 only) Switch between double/single pumping mode;	Manual Controls	**Similar:** The subject and predicate have similar controls. Differences in controls do not raise different questions of safety and effectiveness.
Indicators	Yes, LCD	Yes	**Similar:** The subject device has an LCD display. Differences in visual indicators do not raise different questions of safety and effectiveness.
Power Supply	In: 100 – 240 VAC 50/60 Hz 0.4A Mains Out: 5VDC, 1.5A Batt Out: 3.7VDC 2200mAh	M5, M7, and M12: 6V DC Adaptor or 4 1.5V Batteries M10: 6V DC Adaptor	**Different:** The subject device has a different power supply. Differences in power supply are substantiated by ES/EMC testing and do not raise different questions of safety and effectiveness.
Accessories	Pump body Milk collection container Cushion Tube Milk valve Diaphragm Motor unit Flange	Pump Body Sealing Cover Bottle Cylinder Nipple Membrane	**Different:** The subject device has different packaged components. Differences in onboard accessories do not raise different questions of safety and effectiveness.

The indications for use of the subject and predicate device are identical.

The subject and predicate devices have similar technological features, including design, user interface, vacuum pressure range, cycle speeds, and power source. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including Skin Irritation Testing, Cytotoxicity, and Skin Sensitization testing were performed in accordance with the 2016 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"* and ISO 10993- 1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Skin Sensitization (ISO 10993-10:2010)
- Skin Irritation (ISO 10993-10:2010)

The testing supports the biocompatibility of the device.

Electrical Safety

Testing was conducted in accordance with AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and

essential performance (IEC 60601-1:2005, MOD) and 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.

Electromagnetic Compatibility

Testing was conducted in accordance with IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

Software

Software verification and validation testing was conducted at a "moderate level of concern" as recommended in the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Vacuum level verification testing at each mode/cycle demonstrated that the devices meet mode/cycle specifications.
- Backflow protection testing was conducted to verify liquid does not backflow into the tubing.

10. Conclusion

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