



Food and Drug Administration  
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Silver Spring, MD 20993-0002

December 21, 2015

Wuxi Xinzhongrui Baby Supplies Co., Ltd  
% Diana Hong  
General Manager  
Mid-link Consulting Co., Ltd  
P.O. Box 120-119  
Shanghai, 200120 CN

Re: K151284  
Trade/Device Name: Electric Double Breast Pumps  
Regulation Number: 21 CFR 884.5160  
Regulation Name: Powered Breast Pump  
Regulatory Class: Class II  
Product Code: HGX  
Dated: November 17, 2015  
Received: November 23, 2015

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151284

Device Name

Electric Double Breast Pumps

Indications for Use (Describe)

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.

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 K151284

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

1. Date of Preparation: 12/07/2015
2. Sponsor Identification

**Wuxi Xinzhongrui Baby Supplies Co., Ltd**

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)  
Ms. Betty Xiao (Alternative Contact Person)

**Mid-Link Consulting Co., Ltd**

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4. Identification of Proposed Device

Trade Name: Electric Double Breast Pumps  
Common Name: Powered breast pump  
Models: XB-8636, XB-8703

**Regulatory Information**

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

**Intended Use Statement:**

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.

**Device Description**

The Electric Double Breast Pumps are designed and manufactured to express and collect milk from a lactating woman's breast. Both models, XB-8636 and XB-8703, are electrically powered, software-controlled, digital single-user pumps.

When powered, the XB-8636 starts with stimulation mode for 120 seconds then automatically switches to expression mode for 30 minutes before automatic shutdown. This model has seven suction levels. When powered, the XB-8703 starts with stimulation mode for 180 seconds then automatically switches to expression mode for 30 minutes before automatic shutdown. This model has nine suction levels. Both models allow the user to adjust the suction levels when necessary.

5. Identification of Predicate Device

510(k) Number: K142479  
 Product Name: Megna Breast Pumps  
 Model Name: M10

6. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Devices	Predicate Device
Product Code	HGX	HGX
Regulation No.	21 CFR 884.5160	21 CFR 884.5160
Class	Class II	Class II
Indications for Use	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 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.
Pump Type	Reciprocating Diaphragm	Reciprocating Diaphragm
Pumping Options	Single or Double	Single or Double
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor
Suction Levels	XB-8636: 7 XB-8703: 9	9
Suction Strength	Single & Double: 60 -240 mmHg	Single: 60 - 297 mmHg Double: 60 - 300 mmHg
Cycle Speed	XB-8636: Single: 36 – 103 cycles / min Double: 25 – 76 cycles / min XB-8703: Single: 38 – 120 cycles / min Double: 22 – 68 cycles / min	38 – 139 cycles / min
Suction Flow Rate	XB-8636: Single & Double: 4 – 40 ml / min XB-8703: Single & Double: 4 – 60 ml / min	Single: 9 – 65 ml / min Double: 10 – 67 ml / min
Power Supply	6V DC Adaptor or 4 AA 1.5V batteries	6V DC Adaptor
Back Flow Protection	Yes	Yes

The differences in suction level, suction strength, cycle speed, and suction flow rate between the subject and predicate device do not raise different questions of safety and effectiveness.

## 7. Summary of Non-Clinical Tests

Non-clinical tests were conducted to verify that the proposed device met all design specifications and was 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: 2007, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.

Additionally, the following non-clinical tests were conducted:

- Suction Curves of proposed devices were tested. All the tests results complied with the design specifications of the proposed devices.
- Back flow 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.
- Use-life testing was conducted on the proposed devices. The test result showed there was no significant difference in suction strength or simulating milk suction flow rate of new-manufactured devices and devices after two-year use and 1000 cycles' disinfection.

## 8. Summary of Clinical Tests

Clinical testing was not required to demonstrate substantial equivalence of the Electric Double Breast Pumps to the predicate device.

## 9. Substantially Equivalent (SE) Conclusion

The differences between the Electric Double Breast Pumps and its predicate device do not introduce a new intended use and do not raise different issues of safety and effectiveness. Performance testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended.

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.