DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 26, 2015

Wuxi Xinzhongrui Baby Supplies Co., Ltd.
% David Zeng, Ph.D.
Consultant
Megna, Inc.
1043 Andrew Drive
West Chester, PA 19380

Re: K142479
Trade/Device Name: Megna Breast Pumps (Models M5, M7, M10 and M12)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: January 27, 2015
Received: January 28, 2015

Dear Dr. David Zeng,

This letter corrects our substantially equivalent letter of February 24, 2015.

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" (21CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142479

Device Name
Megna Breast Pumps (Models M5, M7, M10 and M12)

Indications for Use *(Describe)*
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.

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Megna Breast Pumps is provided below.

Device Common Name:	Powered Breast Pump
Device Proprietary Name:	Megna Breast Pumps (Models M5, M7, M10 and M12)
Submitter:	Wuxi Xinzhongrui Baby Supplies Co., Ltd. No.117 Xinhua Road, Meicun, New District Wuxi City, Jiangsu 214000 China Phone: +86-510-81155000 Fax: +86-510-81155898
Contact:	David Zeng, PhD President Megna Inc. 1043 Andrew Drive West Chester, PA 19380 Phone (610) 590-1768 Fax (610) 628-9308 Email: david.zeng@megnainc.com
Date Prepared:	**February 24, 2015**
Classification Regulation:	21 CFR 884.5160
Classification Name:	Powered Breast Pump
Panel:	Obstetrics/Gynecology
Product Code:	**HGX**
Predicate Device:	K113664, Closer to Nature Electric Breast Pump

Indication for Use:

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.

Device Description:

The Megna breast pumps are electrically powered breast pumps for over-the-counter use, intended to be used at home to express a nursing mother's breast milk.

The Megna breast pumps are provided in 4 models:

- Model M5 – Megna Digital Single Breast Pump
- Model M7 – Megna Digital Double Breast Pump
- Model M10 – Megna Digital Double Breast Pump
- Model M12 – Megna Digital Double Breast Pump

Summary of Non-Clinical Testing:

Biocompatibility Testing –

The patient contacting component of all four of the Megna breast pump models is the massage pad on the outer rim of the breast shield. The following biocompatibility testing was conducted on this material:

- Skin irritation test of massage pad ISO 10993-10:2010 – 0.9% sodium chloride extract
- Skin irritation test of massage pad ISO 10993-10:2010 – Sesame oil Extract
- Skin Sensitization Test of massage pad ISO 10993-10:2010 – 0.9% sodium chloride extract
- Skin Sensitization Test of massage pad ISO 10993-10:2010 – 0.9% Sesame Oil Extract
- In Vitro Cytotoxicity Test of massage pad ISO 10993-5:2009

Food Safety Testing for all Milk Contacting Materials -

The milk contacting components of all four of the Megna breast pump models are the cylinder, membrane, nipple, silicone sealant, bottle, pump body and sealing cover.

The following food safety testing was conducted on each of the components:

21 CFR 177.2600 – determining the amount of total extractives from rubber articles intended for repeated use:

- Cylinder, Nipple and Silicone Sealant
- Membrane

21 CFR 177.1520 – determining extractable fraction in n-hexane and soluble fraction in xylene for polypropylene used in contact with food:

- Pump Body
- Sealing Cover
- Bottle

Not Manufactured with BPA -

The device labeling states that it is not manufactured with BPA.

Software Validation –

The software for each of the 4 models was validated in accordance with FDA guidance and product specifications.

Electrical Safety Testing -

The following electrical safety testing was conducted in each of the models:

Model M10–

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1: 2012
- IEC 60601-1-11: 60601-1-11 Edition 1.0 2010-04, 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

Models M5, M7, M12–

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1: 2012
- IEC 60601-1-11: 60601-1-11 Edition 1.0 2010-04, 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

EMC Testing -

The following electromagnetic compatibility testing was conducted on each of the models:

Model M10 –

- EN 60601-1-2:2007+AC:2010, IEC 60601-1-2:2007

Models M5, M7, M12 –

- EN 60601-1-2:2007+AC:2010, IEC 60601-1-2:2007

Performance Testing –

The following performance tests were conducted on all four models:

- Backflow testing showed that no milk is able to back flow into the pump.
- Cleaning Validation Testing showed that after cleaning procedures as recommended in the user manual do not affect device performance.
- Suction curves for each mode for each model show that the device performs to suction strength and cycle speed specifications.

Testing Summary:

The non-clinical testing described above show that the Megna Breast Pumps meet their product specifications and relevant safety testing for their intended use. The testing shows that no new

issues of safety or effectiveness are raised in comparison to the predicate device and therefore support a decision of substantial equivalence.

Substantial Equivalence:

Table 1: Device Comparison Table

	Proposed Device	**Predicate Device**
510(k) Number	TBD	K113664
Submitter	Megna	Mayborn Group Limited
Classification Regulation	884.5160, Class II	884.5160, Class II
Device Name	Megna Breast Pumps (Models M5, M7, M10 & M12)	Closer to Nature Electric Breast Pump
Product Code	HGX	HGX
Indication	The Megna Breast Pumps are intended to express and collect milk from the breast of a lactating woman.	Tommee Tippee Closer to Nature Double Electric Breast Pump is used to express and collect milk from the breast of a lactating woman.
Pumping Options	Single or Double	Single or Double
Back Flow Protection	Yes	Yes
Pump Type	Reciprocating Diaphragm	Reciprocating Diaphragm
Power Supply	M5, M7 & M12: 6V DC Adaptor or 4 1.5V batteries M10: 6V DC Adaptor	9V DC Adaptor or rechargeable 7.4V lithium polymer battery
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor
Number of Suction Levels	M5: 5	5
	M7: 9	
	M10: 9	
	M12: 9	
Suction Strength	M5: Single: 120 - 304mmHg (160 - 405 mbar)	Single: 150 - 285 mmHg (200 - 450 mbar) Double: 97.5 - 210mmHg (130-360 mbar)
	M7: Single & Double: 68 - 300 mmHg (90 – 400 mbar)	

	Proposed Device	Predicate Device
	M10: Single: 60 - 297 mmHg (80 – 395 mbar) Double: 60 – 300 mmHg (80 – 400 mbar)	
	M12: Single: 60- 297 mmHg (80 – 395 mbar) Double: 64 - 297 mmHg (85 – 395 mbar)	
Cycle Speed	M5: 26-80 cycles / min	Fixed: 34 cycles per minute
	M7: 15-68 cycles / min	
	M10: 38 – 139 cycles / min	
	M12: 13-48 cycles / min	
Suction Flow Rate	M5: Single: 20 – 80 ml / min	Single: 32 – 58 ml / min Double: 26 - 54 ml / min
	M7: Single: 20 – 99 ml / min	
	M10: Single: 9 – 65 ml / min Double: 10 – 67 ml / min	
	M12: Single: 10 – 82 ml / min Double: 10 – 83 ml / min	

Substantial Equivalence Summary:

As shown above the subject device and the predicate device are similar in both indications for use and technological characteristics. The differences in suction strength, cycle speed and flow rate are not significant and do not raise new questions of safety or effectiveness. The similarities in indications and technological characteristics, combined with the testing summarized above indicate that the Megna breast pumps can be found substantially equivalent to the predicate device as cleared in K113664.