APR 2 4 2014

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	2013/09/05
Submitter:	Shantou Xinghe Electrical Apparatuses Co., Ltd.
Primary Contact Person:	Jun Deng General Manager Shantou Xinghe Electrical Apparatuses Co., Ltd. Tel: +86-754-83613668-866 Fax: +86-754-83843338
Secondary Contact Person:	Mike Gu Regulatory Affairs Manager OSMUNDA Medical Device Consulting Co., Ltd. Tel: (+86)-20-6232 1333 Fax: (+86) -20-8633 0253
Device:	Trade Name: Horigen, Model XN-2203H2 and Droplet, Model XN-2203H4
Common/Usual Name:	Powered breast pump
Classification Names:	Powered breast pump
Regulation Number:	CFR 884.5160
Product Code:	HGX
Predicate Device(s):	K100435, Ameda Platinum electric breast pump

Device Description:	The Electric Breast Pump, model Horigen, XN-2203H2 and model Droplet, XN2203H4 are designed and manufactured by the Shantou Xinghe Electrical Apparatus Co., Ltd. It is intended to express and collect milk from a lactating woman's breast. This action helps to alleviate engorgement of the breast, maintain the woman's ability to lactate, and provide a mother's milk for future feedings when separation of the mother and baby occur. Two models of this device, Horigen, XN-2203H2 and Droplet, XN-2203H4, are included in this Premarket Notification submission. The primary differences between the two models, Horigen XN-2203H2 and Droplet, XN-2203H4 are the shape of the breast shield and the settings of the stimulating velocity, stimulating intensity, sucking velocity and sucking intensity. The specific settings are listing under the summary of non-clinical tests.
	The product uses a Single-Chip Microcomputer to imitate a baby's suckling action. The device is ergometrically designed to create comfortable milk stimulation, massage, and suction from the breast. Three (3) stimulation levels and five (5) speeds are available to imitate the rhythm and action of a baby's suckling. The control panel is soft and viewing is provided by a LCD screen. Once programmed, the pump's electronic memory stores the selected rhythm and intensity of the device.

Intended Use:	The Electric Breast Pump, model Horigen, XN-2203H2 and model Droplet, XN2203H4 are used to express and collect milk from the breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. The device is intended for single user.

Technology:	The Electric Breast Pump, model Horigen, XN-2203H2 and model Droplet, XN2203H4 are designed to mechanically interface with a mother's breast via a breast shield and withdraw, then collect, the breast milk. The device is driven by a microcomputer which

	electrically controls piston components. The pistons perform a reciprocating movement in the device cylinder and pump seat. A breast cup is fixed between the piston and the piston head on which negative and positive pressure is created by the piston action. A mobile magnet detects the mechanical movement and creates an electrical signal to the microcontroller.

Determination of Substantial Equivalence:

Specification	**Predicate Device**	**Proposed Device**	**Discussion of Differences**
Device Name	**Ameda Platinum Breast Pump**	**Horigen, XN2203H2 and Droplet, XN2203H4**	
K Number	**K100435**	**K132882**	
Indications for Use	The electric breast pump is to express and collect milk from the mother's breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. The electric breast pump is intended for a single user.	The electric breast pump is to express and collect milk from the mother's breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. The electric breast pump is intended for a single user.	Same
Patient Population	Breastfeeding women	Breastfeeding women	Same
5-40°C	5-40°C	5-40°C	Same
Pump Style	Piston	Piston	Same
Vacuum Range	30-250	180 maximum	Similar, the maximum vacuum range of the proposed device is less than the predicated device

Specification	Predicate Device	Proposed Device	Discussion of Differences
			which would not involve any harm.
Cycle Speed	30-80	90 maximum	Similar
Overflow Protection	No	No	Same
Adjustable Section Levels	Yes	Yes	Same
Software	Yes	Yes	Same
Anatomical Sites	Breast	Breast	same
Energy Used and/or Delivered	AC Battery	AC	same
Design and Materials	All food or human contact components are manufactured from materials that meet FDA food additive criteria as set forth in 21 Code of Federal Regulations Part 176, 177 and 178.	All food or human contact components are manufactured from materials that meet FDA food additive criteria as set forth in 21 Code of Federal Regulations Part 176, 177 and 178.	Same
Performance	Stimulation, suction and collection	Stimulation, suction and collection	Same
Standards Met	IEC 60601-1, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General) IEC 60601-1-2, (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)). (General) ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC 60601-1, 3rd Edition IEC 60601-1-2 Edition 3:2007-03 ISO 10993-1:Fourth Edition 2009-10-15 ISO 10993-5:2009 ISO 10993-10; Third Edition 2010-08-01	Same
Biocompatibility	Not cytotoxic,	Not cytotoxic,	Same

Specification	Predicate Device	Proposed Device	Discussion of Differences
	irritating or a dermal sensitizer	irritating or a dermal sensitizer	
Electrical Safety	Electromagnetic compatibility tests are provided to illustrate that electrical safety meets IEC 60601-1-2.	Electromagnetic compatibility tests are provided to illustrate that electrical safety meets IEC 60601-1-2.	Same
Mechanical Safety	Mechanical cycling suction regulator.	Mechanical cycling suction regulator.	Same

Summary of Non-Clinical Tests:

The sponsor has performed bench testing to demonstrate the electric breast pump performs within specifications:

Model Droplet XN-2203H4

Stimulating velocity: 88T/min
Stimulating intensity: -0.018MPa (Max.), 3 adjustable degrees
Sucking intensity: -0.028MPa (Max.), 5 adjustable degrees
Sucking velocity: 34-63T/min, 5 adjustable speeds;

Model Horigen XN-2203H2

Stimulating velocity: 90T/min
Stimulating intensity: -0.012MPa (Max.), 3 adjustable degrees
Sucking intensity: -0.024MPa (Max.), 5 adjustable degrees
Sucking velocity: 35-63T/min, 5 adjustable speeds;

The proposed device has met acceptance criteria of performance testing including: biocompatibility (*InVivo* cytotoxicity, irritation, and sensitization testing) and electrical safety, EMC, and suction level and cycle time.

Conclusion: Shountou Xinghe Electrical Apparatuses Co. Ltd. considers the electric breast pump to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 24, 2014

Shantou Xinghe Electrical Apparatuses Co., Ltd.
Jun Deng
General Manager
NO.8, Yi Road, Pingbei Industrial Zone, Chaoyang District
Shantou, Guangdong 515100
China

Re: K132882
Trade/Device Name: Electric breast pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: March 25, 2014
Received: March 27, 2014

Dear Jun Deng,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner -S

for

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)*
K132882

Device Name

Electric breast pump

Indications for Use *(Describe)*

The electric breast pump is to express and collect milk from breast from the mother's breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. The device is 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
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