March 7, 2019

Guangdong Horigen Mother & Baby Products Co., Ltd.
℅ Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Services Co.,Ltd.
8-9th Floor, R&D Building, No.26 Qinglan Street, Panyu District
Guangzhou, Guangdong 510006
China

Re: K182413
Trade/Device Name: Electric Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 1, 2019
Received: February 4, 2019

Dear Mike Gu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason Roberts -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)*
K182413

Device Name
Electric Breast Pump

Models: XN-2212M2, XN-2219M1, XN-2219M2, XN-2223M1, XN-2223M2, XN-2233M1, XN-2233M2

Indications for Use *(Describe)*
The Electric Breast Pump is intended 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.

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 807.92 the following summary of information is provided:

1. SUBMITTER

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Date prepared	March 6, 2019

2. DEVICE

Device Name:	Electric Breast Pump
Common/Usual Name:	Powered breast pump
Model:	XN-2212M2, XN-2219M1, XN-2219M2, XN-2223M1, XN-2223M2, XN-2233M1 and XN-2233M2
Regulation number	21 CFR 884.5160 Powered breast pump
Regulation Class:	II
Product Code:	HGX Pump, Breast, Powered

3. PREDICATE DEVICE

Predicate device: K143585, Electric Breast Pump

This predicate and the referenced have not been subject to a design-related recall.

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The Electric Breast Pump is designed, manufactured by the Guangdong Horigen Mother & Baby Products Co., Ltd. The device is intended for lactating women in a home setting for a single user. It comprises of a pump unit and the expression collection kit including tubing, and its raw materials include polypropylene, liquid and solid silicone, and thermoplastic elastomer.

This electric breast pump has a negative pressure module that utilizes a single-chip microcomputer. It has multiple stimulation levels for breast massage, and multiple milk expression speed intensities. The keyboard of the control panel is soft. The screen is an LCD or LED screen, allowing for process viewing. The pump's electronic memory takes over, mimicking the rhythm. The electric breast pump is capable of providing vacuum levels from 30 to 247.5 mmHg with cycle rates up to 100 cycles per minute.

The Electric Breast Pump provides the following user features:

- Closed system with anti-backflow
- LCD or LED screen touch button operation
- 2-phase expression: Stimulation and Expression phases
    - Stimulation Phase: Expression pattern with fast cycles (70~100 Cycles/min) and low vacuum (30 ~ 112.5 mmHg) to start milk flowing, 9 levels
    - Expression Phase: Expression pattern with slower cycles (24~90Cycles/min) and higher vacuum (75 ~ 247.5 mmHg) to express milk, 9 levels
- Double-pumping ability: single or double pumping
- Dual power source: it can be operated by A/C adapter or batteries
- Built-in rechargeable li-ion polymer battery or additional AA battery power option

5. INDICATIONS FOR USE

The Electric Breast Pump is intended 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 indications for use statement for the subject device is similar to that of the predicate, with minor alterations in text; however, the intended use of the subject and predicate devices is the same (express and collect milk from breasts of lactating women).

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device & Predicate Device(s):	**K182413**	**K143585**
General Device Characteristics		
Environment of Use	Home	Home, institutions and hospital
Single or Multiple-User	Single	Single
Pump Type	diaphragm pump	diaphragm pump
Adjustable Vacuum Levels	9 levels	9 levels
Maximum Expression Intensity	247.5	270
Stimulation Intensity range	30-112.5	15.2-144.4
Stimulation Velocity	70– 100 cycles/min	95-105
Expression Velocity	24 – 90 cycles/ min	20-65
User Interface	Hardware interface	Hardware interface
Backflow Protection (prevention of backflow of liquid into pump/tubing)	Yes	Yes
Overflow Protection (stops pumping when the bottle is full to prevent overflow)	No	No
Power Source	AC Mains 100-240 VAC, 50/60Hz, 1.5A/1A 4AA Alkaline battery Rechargeable Li-Ion Battery (7.4 V / 1750 mAh)	4AA battery or AC/DC adapter

The subject device is different from the predicate and the referenced in suction pressure range, cycle speed, maximum suction pressure and the power source. However, these differences do not raise different questions of safety and effectiveness. The technological differences can be evaluated through the software, performance and EMC/electrical safety testing provided.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Electric Breast Pump was conducted in accordance with the International Standard ISO 10993-1:2009, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

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

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Electric Breast Pump. The device complies with the IEC 60601-1:2012, standard for electrical safety and the IEC 60601-1-2:2014 standard for EMC. Software Validation was performed per the FDA Guidance: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

Performance testing

Performance testing was conducted on the Electric Breast Pump. Technical parameters of stimulation mode and expression mode, including working current, pressure, cycle rate and noise, backflow protection mechanism, and battery specification were evaluated in the performance testing. In addition, the stability of vacuum level and shelf life were evaluated. All of the tested parameters met the predefined acceptance criteria.

8. CONCLUSION

The indications for use statement for the subject device is similar to that of the predicate. The differences between the Electric Breast Pump and its predicate device

do not raise new issues of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that the Electric Breast Pump should perform as intended in the specified use conditions.

From the results of non-clinical data including the performance testing described, Guangdong Horigen concludes that the Electric Breast Pump is as safe and as effective as the predicate device.