May 4, 2021

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

Re: K201152
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 29, 2021
Received: April 2, 2021

Dear Olivia Meng:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201152

Device Name
Electric Breast Pump

Indications for Use *(Describe)*
The Electric Breast Pump is intended to be used by lactating women to express and collect milk from their 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. It is intended for a single user in a home or hospital 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

K201152

1. SUBMITTER

Name:	Guangdong Horigen Mother & Baby Products Co., Ltd.
Address:	No. 18, Pingnan Industrial Zone, Mianbei Street, Chaoyang District, 515100 Shantou, Guangdong, China
Phone:	+86-754-83613668
Fax:	+86-754-83843338
Primary Contact Person:	Olivia Meng Regulatory Affairs Manager Guangzhou Osmunda Medical Device Technical Service Co., Ltd. Tel: (+86)-20-6231 6262 Fax: (+86) -20-8633 0253
Secondary Contact Person:	Changxin Chen General Manager Assistant Guangdong Horigen Mother & Baby Products Co., Ltd. Tel: (+86)-754-83613668-866 Fax: (+86)-754-83843338
Date prepared:	May 3, 2021

2. DEVICE

Device Name/Trade Name:	Electric Breast Pump
Models:	XN/MS-2224A and XN/MS2224B
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

3. PREDICATE DEVICE

510(k) Number:	K181784
Manufacturer:	Uzinmedicare Co.
Device Name:	Spectra S3 Plus Breast Pump
	The predicate device has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

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. This Electric Breast Pump is intended for a single user in a home or hospital environment.

The Electric Breast Pump has two models: XN/MS-2224A and XN/MS-2224B. Both models are capable of single and double pumping and have two modes: stimulation and expression mode. Both models can be operated using AC power, a built-in rechargeable li-ion polymer battery, or AA batteries.

5. INDICATIONS FOR USE

The Electric Breast Pump is intended to be used by lactating women to express and collect milk from their 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. It is intended for a single user in a home or hospital environment.

6. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS

The following table compares the subject device to the predicate device with respect to the indications for use and technological characteristics:

Specification	**Subject Device** Electric Breast Pump K201152		**Predicate Device** Spectra S3 Plus Breast Pump K181784
Indications for Use	The Electric Breast Pump is intended to be used by lactating women to express and collect milk from their 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. It is intended for a single user in a home or hospital environment.		The Spectra 3 Plus Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Spectra 3 Plus Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.
Patient Population	Lactating women		Lactating women
Use Environment	Hospital and home		Hospital and home
Pump Style	Diaphragm pump		Diaphragm pump
Pumping Option	Single or Double		Single or Double
Adjustable Levels (Stimulation Mode)	Suction Strength	XN/MS-2224A: 7 levels XN/MS-2224B: 7 levels	12 levels
	Cycle Speed	XN/MS-2224A: 3 levels XN/MS-2224B: 3 levels	N/A
Adjustable Levels (Expression Mode)	Suction Strength	XN/MS-2224A: 10 levels XN/MS-2224B: 12 levels	12 levels
	Cycle Speed	XN/MS-2224A: 6 levels XN/MS-2224B: 6 levels	N/A

Cycle speed (cycles/min) Stimulation Mode	XN/MS-2224A: 70-105 XN/MS-2224B: 70-105	38-70
Suction Strength (mmHg) Stimulation Mode	XN/MS-2224A: Single 37.5-187.5 mmHg Double 15-105 mmHg XN/MS-2224B: Single 37.5-187.5 mmHg Double 15-105 mmHg	50 (±50) mmHg to 270 (-50 mmHg)
Cycle speed (cycles/min) Expression Mode	XN/MS-2224A: 34-54 XN/MS-2224B: 34-54	38-70
Suction Strength (mmHg) Expression Mode	XN/MS-2224A: Single 75-247.5 mmHg Double 15-195 mmHg XN/MS-2224B: Single 75-247.5 mmHg Double 15-225 mmHg	50 (±50) mmHg to 270 (-50 mmHg)
Maximum Suction Strength (mmHg)	247.5	270
Backflow protection	Yes	Yes
Visual indicator	LED Display	LCD Display
Power source	a. AC/DC adapter b. Rechargeable li-ion battery	a. AC/DC Adapter b. Rechargeable li-ion battery

The subject and predicate device have similar indications for use statements. They both are intended to be used to express and collect milk for the breast of lactating women.

The subject and predicate device have different technological features, including the user interface, expression levels, suction strength, cycle speed, and power source. These technological differences do not raise different questions of safety or effectiveness.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following performance data were provided in support of a substantial equivalence determination:

a. Electrical Safety and Electromagnetic Compatibility:
   - IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance with US deviations per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012.
   - 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.

- IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility
- IEC 62133:2012 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

b. Biocompatibility:
Biocompatibility testing in accordance with the FDA guidance "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" dated September 4, 2020. Testing included the following assessments:
   - Cytotoxicity per ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
   - Sensitization per ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
   - Irritation per ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

   The user-contacting materials were shown to be non-cytotoxic, non-sensitizing, and non-irritating.

c. Software Verification:
   - Software verification and validation in accordance with the FDA Guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005.

d. Performance testing:
   - Vacuum pressure and cycle rate testing was conducted at all settings for each device model.
   - Backflow testing was conducted to demonstrate that liquid does not backflow into the tubing/pump.
   - Use life testing of vacuum level and battery performance
   - Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.

8. CONCLUSION

The nonclinical performance testing described above demonstrate that the Electric Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.