May 6, 2022

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: K212564
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 31, 2022
Received: April 7, 2022

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,

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212564

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 breasts, to alleviate engorgement of the breasts, 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 multiple users in a hospital setting. It is also intended for home use by 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 – K212564

1. Submitter Information

Applicant: Guangdong Horigen Mother & Baby Products Co. Ltd.
Address: No. 18, Pingnan Industrial Zone, Mianbei Street, Chaoyang District, 515100 Shantou, Guangdong, China
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2. Correspondent Information

Contact: Olivia Meng
Regulatory Affairs Manager
Phone: + 86 (754) 836-13668
Email: hui.meng@osmundacn.com

3. Date prepared: May 5, 2022

4. Device Information

Device Name:	Electric Breast Pump
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

5. Predicate Device Information

Device Name:	Spectra 3 Plus Breast Pump
510(k) Number:	K181784
Manufacturer:	Uzinmedicare Co.

The predicate device has not been subject to a design-related recall.

6. Device Description

The Electric Breast Pump is a multi-user electric breast pump designed for lactating women to express and collect milk from the breast. It is intended for use in the hospital and home environments and can also be used by a single user. The device is an electrically powered pump consisting of the following key components: a flange, breast shield body, silicone diaphragm, tubing/tubing connector, pump motor, AC/DC adapter, and milk collector. The Electric Breast Pump contains two models, SMG and GEA. Both models can be operated in single and double pumping modes while connected to AC power and have an onboard rechargeable lithium-ion battery.

The SMG model has an LCD display, and the user can select between stimulation or expression mode. Stimulation mode has 5 vacuum levels and expression mode has 16 vacuum levels. For every vacuum level, the user can independently select among 9 cycle speed levels (for stimulation) and 16 cycle speeds (for expression up to vacuum level 11; higher vacuum levels have less available cycle speeds). The SMG model is wirelessly operable via Bluetooth connection to a smart device.

The user can record a pumping session, tracking any changes to vacuum levels, cycle speeds, and their duration for up to 2 "pumping programs." The display presents the vacuum level, cycle level, timer, battery status symbol, Bluetooth symbol, external power connected indicator, indicators for programmed pumping sessions, and images reflecting whether the user is in the stimulation or expression phase.

The GEA model also has an LCD display, and the user can select stimulation or expression mode. Stimulation mode and expression mode have 10 levels. Stimulation speed is set to 70 cycles per minute, whereas expression mode allows for cycling speed between 3 levels.

Similarly, the user can record a pumping session, tracking any changes to vacuum levels, cycle speeds, and their duration. The pump can record 1 "pumping program." The display presents the vacuum level, cycle level, timer, battery status symbol, external power connected indicator, indicators for programmed pumping sessions, and images reflecting whether the user is in the stimulation or expression phase.

Both devices operate via an electric negative pressure module that runs discontinuously to generate periodic negative pressure suction and are controlled by a magnetic valve for negative pressure adjustment. Each vacuum pump operates with a DC motor and corresponding DC power supply. Both devices have a 40 min stimulation and expression session duration. To prevent milk from flowing into the vacuum, a backflow protection mechanism physically separates the milk-contacting pathway from the vacuum system.

Only the silicone cushion and breast shield body components are in direct contact with the skin and breast tissue. All other components (i.e., motor unit) of the subject device are not in contact with the breast.

The subject device components are made of the following materials:

- Dust cover, Breast Shield Body, Cap, Bottle, Bottle Adapter, Bottle Lid, Disc Collar, Nipple Dust Cover, Bottle Stand: Polypropylene
- Cushion/Flange, diaphragm, nipple, diaphragm: Silicone
- Tubing: Silicone

7. Indications for Use

The Electric Breast Pump is intended to be used by lactating women to express and collect milk from their breasts, to alleviate engorgement of the breasts, 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 multiple users in a hospital setting. It is also intended for home use by a single user.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 1: Comparator Table for Subject and Predicate Devices

	Electric Breast Pump K212564 Subject Device	**Spectra 3 Plus Breast Pump K181784 Predicate Device**	**Comparison**
Product Name	Electric Breast Pump	Spectra 3 Plus Breast Pump	**N/A**
Product Code	HGX	HGX	**Same**
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	**Same**

Regulatory Class	Class II	Class II	**Same**
Patient Population	Lactating Women in a Home or Hospital Setting.	Lactating Women in a Home or Hospital Setting.	**Same**
Indications for Use	The Electric Breast Pump is intended to be used by lactating women to express and collect milk from their breasts, to alleviate engorgement of the breasts, 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 multiple users in a hospital setting. It is also intended for home use by a single user.	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.	**Same**
Pump Options	Single or Double	Single or Double	**Same**
Cycling control mechanism	Microcontroller	Microcontroller	**Same**
Backflow Protection	Yes	Yes	**Same**
Suction Modes	Stimulation Mode and Expression Mode	Massage Mode and Expression Mode	**Similar**
Suction levels	SMG: 16 Level Expression 5 Level Stimulation GEA: 10 Level Expression and Stimulation	5 level Massage 12 levels Expression	**Different:** The differences in suction levels for each mode do not raise different questions of safety and effectiveness.
Adjustable suction levels	Yes	Yes	**Same**
Vacuum range: Stimulation	SMG: 45 – 165 (±7.5) mmHg Single 15 – 98 (±7.5) mmHg Double GEA: 30 – 135 (±7.5) mmHg Single 15 – 83 (±7.5) mmHg Double	50 (± 50) – 270 (-50) mmHg	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in maximum suction pressure were substantiated by performance testing below.
Vacuum range: Expression	SMG: 45 – 240 (±7.5) mmHg Single 15 – 195 (±7.5) mmHg Double GEA: 60 – 240 (±7.5) mmHg Single 30 – 195 (±7.5) mmHg Double	50 (± 50) – 270 (-50) mmHg	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in maximum suction pressure were substantiated by performance testing below.
Cycle Speed: Stimulation	SMG: 72 – 104 (±5) cycles/min GEA: 70 (±5) cycles/min	38 – 70 cycles/minute	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in cycle speed were substantiated by performance testing below.
Cycle Speed: Expression	SMG: 40 – 70 (±5) cycles/min GEA: 24 – 70 (±5) cycles/min	38 – 70 cycle/minute	**Different:** The difference in specification does not raise different questions of safety and effectiveness. Differences in cycle speed were substantiated by performance testing below.
Controls	LCD, push buttons	LCD, push buttons	**Similar:** The subject and predicate have similar controls. Differences

			in controls do not raise different questions of safety and effectiveness.
Power Supply	AC and battery SMG: - AC: 100-240 V AC, 50/60 Hz and an output of 15 V / 1.6 A DC - Battery: 11.1 V 2,000 mAh Li-ion GEA: - AC: 100-240 V AC, 50/60 Hz and an output of 5 V / 2 A - Battery: 3.7 V 2700 mAh Li-ion	AC: 100-240 V AC, 50/60 Hz, 600mA and an output of 12 V / 2 A DC Battery: 11.1 V 2,000 mAh Li-ion Polymer	**Similar:** Both devices are operable while connected to AC power and internally via rechargeable battery. On their own, differences in power source specifications do not raise different questions of safety and effectiveness.
Mobile Application and Wireless functionality	SMG: Bluetooth connectivity GEA: None	None	**Different:** The SMG subject device has Bluetooth wireless functionality. Differences in wireless technology do not, on their own, raise different questions of safety and effectiveness.

The indications for use of the subject and predicate device are similar, with only minor differences in wording. The intended use environments for both the subject and predicate devices are the same.

The subject and predicate devices have similar technological features, including device design, user interface, materials, and power source. As noted in the table above, the different technological characteristics of the subject device do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including irritation, cytotoxicity, and sensitization testing were performed in accordance with the 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process"* and ISO 10993- 1:2009 as follows:

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

The testing supports the biocompatibility of the device. The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

Electrical Safety

Testing was conducted in accordance with AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD), IEC 62133-2:2017, 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 - Part 2: Lithium systems, and 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.

Electromagnetic Compatibility
Testing was conducted in accordance with IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

Software
Software was evaluated as recommended in the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Performance Testing
Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Vacuum level verification testing at each mode/cycle demonstrated that the devices meet mode/cycle specifications.
- Backflow protection testing was conducted to verify liquid does not backflow into the tubing.
- Cross Contamination testing was conducted to verify the pump could not be contaminated or damaged by multiple users.
- Use life testing was conducted to demonstrate that the device maintains its specifications throughout its proposed use life.
- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.

10. Conclusion

The subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.