September 11, 2020

Guangdong Horigen Mother & Baby Products Co., Ltd
Jun Deng
Vice President
No. 18, Pingnan Industrial Zone, Mianbei Street,
Chaoyang District
Shantou, 515100
China

Re: K193449
Trade/Device Name: Electric Breast Pump (model KP033_01), Electric Double Breast Pump (model KP053_01)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: August 8, 2020
Received: August 10, 2020

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. 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.
Acting 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)*
K193449

Device Name
Electric Breast Pump (model KP033_01)

Electric Double Breast Pump (model KP053_01)

Indications for Use *(Describe)*
The Electric Breast Pump (model KP033_01), Electric Double Breast Pump (model KP053_01) are 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 (model KP033_01), Electric Double Breast Pump (model KP053_01) are 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 – K193449

I. SUBMITTER:

510(k) Owner:
Guangdong Horigen Mother & Baby Products Co., Ltd.
No. 18, Pingnan Industrial Zone, Mianbei Street,
Chaoyang District, 515100 Shantou, Guangdong,
PEOPLE'S REPUBLIC OF CHINA

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Date summary prepared: September 8, 2020

II. DEVICE

Device Name: Electric Breast Pump (model KP033_01),
Electric Double Breast Pump (model KP053_01)
Common Name: Powered Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Product Code: HGX (Pump, Breast, Powered)
Regulatory Class: II

III. PREDICATE DEVICE

The predicate device is the Electric Breast Pump (K182413).

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

IV. DEVICE DESCRIPTION

The Electric Breast Pump (model KP033_01), Electric Double Breast Pump (model KP053_01) are electric breast pumps that are intended for lactating women to express and collect breast milk. The Electric Breast Pump and Electric Double Breast Pump are intended for a single user and are to be used in the home environment.

The Electric Breast Pump (model KP033_01), Electric Double Breast Pump (model KP053_01) are Li-ion-battery powered breast pumps that include following main components: the expressed milk collection kit, the pump unit, and tubing. The expressed milk collection kit includes a funnel cover, silicone cushion, funnel

adapter, membrane, valve body, valve membrane, membrane cap, and milk bottle. The pump unit contains a chip that controls the work of the vacuum pump and solenoid valve to draw air inside of the funnel adapter to form negative pressure. The tubing has two connectors on the two ends. The user attaches the connector to the air vent of the membrane cap and the connector to the pump unit separately to ensure a tight fit.

DEVICE MODELS:

- KP033_01: Single pump
- KP053_01: Double pump

V. INDICATIONS FOR USE

The Electric Breast Pump (model KP033_01), Electric Double Breast Pump (model KP053_01) are 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 (model KP033_01), Electric Double Breast Pump (model KP053_01) are intended for a single user.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICE

DEVICE	**Subject Device**	**Primary Predicate Device**
Product Name	Electric Breast Pump (model KP033_01), Electric Double Breast Pump (model KP053_01)	Electric Breast Pump
Indications for Use	The Electric Breast Pump (model KP033_01), Electric Double Breast Pump (model KP053_01) are 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 (model KP033_01), Electric Double Breast Pump (model KP053_01) are intended for a single user.	The Electric Breast Pump (K182413) 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.

Classification Product Code	HGX	HGX
Single User	Yes	Yes
Single/Double Pump	Single or Double Pump	Single
Environment of Use	Home	Home
Pump Type	Diaphragm pump	Diaphragm pump
Adjustable Vacuum Levels	9 Levels	9 Levels
Backflow Protection (prevention of backflow of liquid into pump/tubing)	Yes	Yes
Maximum Expression Pressure	247.5mmHg	247.5mmHg
Stimulation Pressure range	KP033_01 (30-120, mmHg) KP053_01 (37.5-112.5mmHg)	30-120 mmHg
Stimulation Velocity	100 Cycles/min	100 cycles/min
Expression Velocity	26-60 Cycles/min	20 – 90 cycles/ min
Expression Pressure Range	120 -247.5 mmhg	75-247.5mmhg

The intended use of the subject and predicate devices is the same (express and collect milk from breasts of lactating women). The subject device has different adjustable stimulation levels and a different power source as compared to the predicate device. There are minor differences in stimulation and expression pressure ranges and cycle speeds of stimulation and expression. However, these differences do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

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

Biocompatibility

A biocompatibility evaluation for the subject device 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 subject device in accordance with IEC 60601-1:2012 (electrical safety) and IEC 60601-1-2:2014 (EMC).

Software

Software verification and validation for the subject device was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (2005).

Performance testing

Performance testing was conducted on the subject device, including the following assessments:

- Minimum and maximum vacuum pressure testing in single and double pumping mode
- Assessment of technical specifications for stimulation mode and expression mode at all cycle and vacuum settings
- Assessment of working current, pressure, cycle rate and noise
- Backflow protection mechanism testing
- Battery specification validation and performance
- Use life testing of vacuum level and battery performance

All of the tested parameters met the predefined acceptance criteria.

VIII. CONCLUSION

The nonclinical performance data described above demonstrate that the Electric Breast Pump (model KP033_01), Electric Double Breast Pump (model KP053_01) is as safe and effective as the predicate device and supports a determination of substantial equivalence.