DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 8, 2016

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

Re: K162747
Trade/Device Name: Proture Double Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: Class II
Product Code: HGX
Dated: October 9, 2016
Received: October 11, 2016

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. 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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

For Division

Douglas Silverstein -S
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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)*
K162747

Device Name
Proture Double Electric Breast Pump

Indications for Use *(Describe)*
The Proture Double Electric Breast Pump is a powered breast pump to be used by lactating women in a home setting to express and collect milk from their breasts. This device 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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Secondary Contact Person:	Mike Gu Regulatory Affairs Manager Guangzhou Osmunda Medical Device Technical Service Co., Ltd. Tel: (+86)-20-6231 6262 Fax: (+86) -20-8633 0253
Date prepared	Sep 27, 2016

2. DEVICE

Device Name:	Proture Double Electric Breast Pump
Common/Usual Name:	Powered breast pump
Regulation number	21 CFR 884.5160 Powered breast pump
Regulation Class:	II
Product Code:	HGX Pump, Breast, Powered

3. PREDICATE DEVICE

K160511, Naya Breast Pump System
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The Proture Double 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 and is for a single user. It comprises 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 imitates baby's sucking rhythm with help of a single-chip microcomputer. It has multiple stimulation levels for breast massage, and multiple milk suction speed intensities to imitate rhythm of a baby's suction. The keyboard of the control panel is soft. The screen is an LCD, 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 15 to 247 mmHg with cycle rates up to 107 cycles per minute.

The Proture Double Electric Breast Pump provides the following user features:

- Closed system with anti-backflow
- LCD screen touch button operation
- 2-phase expression: Stimulation and Expression phases
    - Stimulation Phase: Suction pattern with fast cycles (53-107 cycles/min) and low vacuum (15-120mmHg) to start milk flowing, 5 levels
    - Expression Phase: Suction pattern with slower cycles (19~47T/min) and higher vacuum (82-247mmHg) 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

All parts of the device that directly contact with breast and milk are to be sanitized by boiling in water for 5 minutes, followed by drying with a clean towel. After use, all parts that directly contact the breast and milk are to be cleaned in warm, soapy water.

5. INDICATIONS FOR USE

The Proture Double Electric Breast Pump is a powered breast pump to be used by lactating women in a home setting to express and collect milk from their breasts. This device is intended for a single user.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 6.1 Comparison with Predicate Device

Specification	Predicate Device	Proposed Device	Discussion of Differences
Device name	Naya Breast Pump System	Proture Double Electric Breast Pump	
K number	K160511	K164727	
Product code	HGX	HGX	Identical
Indication for Use	The Naya Breast Pump System is a powered breast pump to be used by lactating women in the hospital or home setting to express and collect milk from their breasts.	The Proture Double Electric Breast Pump is a powered breast pump to be used by lactating women in a home setting to express and collect milk from their breasts. This device is intended for a single user.	Different. The proposed device is only for single users in a home environment. Same Intended Use
Patient Population	Lactating women	Lactating women	Identical
Environment of Use	Home and Hospital	Home	Different. The proposed device is only intended for a home environment. Same Intended Use
Pump Style	Reciprocating Pump	Reciprocating Pump	Identical
Single/double pump	both	both	Identical
Adjustable suction levels	10 levels	9 levels	Similar. Less suction levels. This difference does not raise different questions of safety and effectiveness.
Cycle speed (cycles/min)	34–120	19-107	Similar. Lower cycle speed. This difference does not raise difference questions of safety and effectiveness.
Visual indicator	a mobile App	LCD Screen	Different. Different user interface. This difference does not raise different questions of safety and effectiveness.

Specification	Predicate Device	Proposed Device	Discussion of Differences
Vacuum range (mmHg)	50-260	15-247	Similar. Lower vacuum levels. This difference does not raise difference questions of safety and effectiveness.
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor	Identical
Power source	Input: 100-240 VAC, 50/60Hz,2.1A Rechargeable Li-ion Battery	Input: 100-240 V, 50/60Hz, 1.6A Battery or A/C Adapter	Similar. Different batteries. Complied with IEC 60601-1 and IEC 60601-1-2. This difference does not raise different questions of safety and effectiveness.
Software	Yes	Yes	Identical
Anatomical Sites	breast	breast	Identical
Cleaning method for Accessories	Soap and warm water	Soap and warm water	Identical
Materials in contact with user and expressed milk tested per ISO 10993-1	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Identical
Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC60601-1-2 IEC60601-1-11	Identical

According to the above comparison, the proposed device is comparable to the predicate device in pump style, single/double pump, cycling/suction control mechanism, anatomical sites, cleaning method for accessories, biocompatibility and electrical safety.

Compared with the predicate device, the proposed device is indicated for single users in a home environment, while the predicate device is indicated for use by single or multiple users in a home or hospital environment. These differences in physical location of use do not impact the intended use (expressing and collecting milk from breasts), which is the same for the proposed and predicate devices.

In terms of technology compared with the predicate device, the proposed device has less suction levels, different cycle speeds, different vacuum range, a different device interface, and type of batteries. However, as noted in the table above, these differences in technological characteristics do not raise different questions of safety and effectiveness as compared to the predicate device.

7. PERFORMANCE DATA

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

Biocompatibility testing

The biocompatibility evaluation for the Double Electric Breast Pump was conducted in accordance with the International Standard ISO 10993-1:2009/(R)2013, "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
- Sensitization
- Skin Irritation

The breast shield body and silicone cushion of the Proture Double Electric Breast Pump are considered to contact directly with the human body and breast milk for a duration of less than 24 hours. Testing for cytotoxicity, sensitization and skin irritation complied with ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity and ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. Testing demonstrates that the materials are non-cytotoxic, non-sensitizing, and non-irritating.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Proture Double Electric Breast Pump. The device complies with the IEC 60601-1:2012, standard for electrical safety and the IEC 60601-1-2:2007 standard for EMC. It demonstrates substantial equivalences to the predicate device.

Performance testing

Performance testing was conducted on the Proture Double Electric Breast Pump. Technical parameters of stimulation mode and suction mode, including working current, pressure, cycle rate and noise were evaluated in the performance testing, as well as the stability of vacuum level and use-life. All of the tested parameters meet the predefined acceptance criteria. The performance parameters were compared with the predicate device in Table 6.1, and it is concluded that the proposed device is substantially equivalent to the predicate device.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern. Software validation demonstrated that the software functions as specified in the software requirement specifications. It demonstrates substantial equivalences to the predicate device.

Animal Study

The subject of this premarket submission, Proture Double Electric Breast Pump, does not require animal studies to support substantial equivalence.

Clinical Study

The subject of this premarket submission, Proture Double Electric Breast Pump, did not require clinical studies to support substantial equivalence.

8. CONCLUSION

The differences between the Proture Double 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 Proture Double 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 Proture Double Electric Breast Pump is as safe and as effective as the predicate device.