DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 2, 2017

Nantong Poly Technology Co., Ltd.
% Jonathan Hu
Technical Manager
Medwheat (Shanghai) Medical Technology Co.,Ltd.
Yangpu District Liaoyuan East Road Shuangyang
First Suite No.33 Room 303
Shanghai, 200093
China

Re: K163183
Trade/Device Name: Yooeehouse Breast Pump (Models: S08, S10, L08, L10)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: August 15, 2017
Received: August 22, 2017

Dear Jonathan Hu:

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,

Benjamin R. Fisher -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K163183

Device Name
Yooeehouse Breast Pump (Models: S08, S10, L08, L10)

Indications for Use *(Describe)*
The Yooeehouse breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for single users.
The Yooeehouse pumpset should be used in combination with Yooeehouse breast pump and is intended to be used by lactating women to express and collect milk from their breast. The pumpset can be used both as a single pumpset and as a double pumpset.

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.

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510(k) Summary

Submitter's Information

Name of Sponsor: Nantong Poly Technology Co., Ltd.
No.332, Xinxing R o a d , Development Zone, Nantong, Jiangsu, China
Contact Name: Rongmin Lin
Telephone No.: 86-0513 81528229
Fax No.: 86-0513 81528229
Email Address: lin_11000@126.com

Date Prepared

September 28, 2017

Correspondent's Information

Company Name: Medwheat (Shanghai) Medical Technology Co., Ltd.
Address: Yangpu District Liaoyuan East Road Shuangyang, First Suite No, 33, Room 303, Shanghai, China
Correspondent Name: Jonathan Hu
Telephone No.: 86-021-65181421
Email Address: Jonathan.hu@medwheat.com

Device Name and Classification

Trade Name: Yooeehouse Breast Pump
Model Names: S08, S10, L08, L10
Common Name: Powered Breast Pump
Classification Number: 21 CFR 884.5160
Classification Name: Powered Breast Pump
Product Code: HGX (Pump, Breast, Powered)
Regulatory Class: II

Identification of Predicate Device(s)

K141742 - Ardo Carum and Calypso Powered Breast Pumps

The predicate devices have not been subject to a design-related recall.

Description of the Device

The subject device is a breast pump that is intended to be a single patient reusable device. The device is used in a home environment and is capable of single and dual pumping. The submission includes four different breast pumps: L08, L10, S08, and S10.

The breast pump uses a USB adapter. The breast pump consists of a pump, a non-sterile pumpset (composed of silicone, polypropylene, acrylonitrile butadiene styrene, and polyphenylene sulfone), and a power adapter. The breast pump has a negative pressure

module that utilizes a microcomputer-controlled system to set and adjust the mode (massage or expression), velocity and intensity of stimulation and suction. The vacuum pump component of the device creates the negative pressure used to extract milk from the breast. The vacuum pump is connected to a solenoid valve that provides variable vacuum cycling rates ranging from 24-110 cycles/minutes. In the massage mode, there is single vacuum pressure of 30 mmHg, while the expression mode has vacuum pressures ranging from 60 to 220 mmHg depending on the expression setting selected. A light-emitting diode indicator (Models S08 and S10) or liquid-crystal display (models L08 and L10) indicate the status of operation.

Indication for Use

The Yooeehouse breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for single users.

The Yooeehouse pumpset should be used in combination with Yooeehouse powered breast pumps and is intended to be used by lactating women to express and collect milk from their breast. The pumpset can be used both as a single pumpset and as a double pumpset.

Comparison of Indication for Use with Predicate Device

	K 163183	**K141742**
Indications for Use	The Yooeehouse breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for single users. The Yooeehouse pumpset should be used in combination with Yooeehouse powered breast pumps and is intended to be used by lactating women to express and collect milk from their breast. The pumpset can be used both as a single pumpset and as a double pumpset.	The ARDO Carum powered breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for multiple users. The ARDO Calypso breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for single users. The ARDO Pumpset should be used in combination with ARDO breast pumps and is intended to be used by lactating women to express and collect milk from their breast. The Pumpset can be used both as a single pumpset and as a double pumpset

The subject device's indication for use statement is not identical to the predicate device. The predicate device has separate indication for use statements for each version included in the predicate submission; however, both the subject and predicate device have the same intended use – to express and collect milk from lactating women for breast feeding.

Comparison of Technological Characteristics with Predicate Device

Device & Predicate Device(s):	K163183				K141742
General Device Characteristics					
Models	S08	S10	L08	L10	
Code	HGX	HGX	HGX	HGX	HGX
Single User	Yes	Yes	Yes	Yes	Carum : multiuser Calypso: single user
Single/double pump	Single or double	Single or double	Single or double	Single or double	Single or double
Pump Type	Micro air pump	Micro air pump	Micro air pump	Micro air pump	Micro air pump
Media separation (backflow protection)	Valve	Valve	Valve	Valve	Valve
Expression pattern	2- phase	2- phase	2- phase	2- phase	2- phase
Specifications					
Power supply	Micro USB	Micro USB	Micro USB	Micro USB	Carum: AC or rechargeable Calypso: Rechargeable battery
Suction levels (massage/stimulation)	1	1	1	1	7 (Carum)
Suction levels (expression)	9	9	9	9	8
Suction Strength (expression)	60- 220 mmHg	60- 220 mmHg	60- 220 mmHg	60- 220 mmHg	Carum: 22-250 mmHg Calypso: 37-250 mmHg
Suction levels (Expression)	9	9	9	9	8
Cycles per minutes (expression)	24-65	24-65	24-65	24-65	30-60
Visual indicator	LED	LED	LCD	LCD	LCD

The subject device and the predicate device do not have the same technological characteristics. The maximum vacuum pressure, suction levels, cycle speed, and power supply are different between the subject device and the predicate device. These differences do not raise different questions of safety and effectiveness, and can be addressed through performance testing.

Non-Clinical Performance Test Summary

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination:

- Bench Testing
    - Backflow Protection Testing: Performance testing was conducted to assess backflow protection of the subject device (i.e., prevention of milk ingress into the pump tubing or pump).
    - Vacuum Profile Testing: Performance testing was conducted at minimum and maximum vacuum settings to determine the minimum and maximum vacuum levels of the pump as compared to its specifications. The specifications were met for vacuum level, cycle rate, and backflow protection. Testing was conducted under single and double pumping conditions with appropriate power sources.
    - Durability testing: performance testing was conducted to assess use-life of the device.
- Electrical Safety
    - AAMI / ANSI ES60601-1:2005/ (R) 2012 and A1:2012, C1:2009/(R) 2012 and

A2:2010/(R) 2012
    - IEC 60601-1-11:2015
- Electromagnetic Compatibility
    - IEC 60601-1-2:2014
- Biocompatibility
    - Sensitization - ISO 10993-10:2010
    - Irritation - ISO 10993-10:2010
    - Cytotoxicity - ISO10993-5:2009
- Software Validation
    - FDA Guidance: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

Conclusion

Based on the comparison and analysis above, the Yooeehouse Breast Pump is substantially equivalent to the predicate device.