December 20, 2017

Joytech Healthcare Co., Ltd.
Ren Yunhua
General manager
No.365, Wuzhou Road, Yuhang Economic Development Zone
Hangzhou City, Zhejiang 311100
China

Re: K172989
Trade/Device Name: Electric Breast Pump (Models LD-202 and LD-213)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: September 15, 2017
Received: September 27, 2017

Dear Ren Yunhua:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

For 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)*
K172989

Device Name
Electric Breast Pump (Models LD-202 and LD-213)

Indications for Use *(Describe)*

The Electric Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Electric Breast Pump 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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JOYTECH HEALTHCARE CO. LTD.

510(k) Summary

K172989

1. Date Prepared: 2017.12.19

2. Submitter's Identification:

Name: JOYTECH HEALTHCARE CO., LTD.

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3. Name of the Device:

Trade Name: Electric Breast Pump (Models LD-202, LD-213)

4. Classification Information:

Common Name: Electric Breast Pump

Classification name: Powered breast pump

Regulation number: 884.5160

Product Code: HGX, Powered breast pump

Device Class: II

Panel: Obstetrics/Gynecology

JOYTECH 健拓 JOYTECH HEALTHCARE CO. LTD.

5. Predicate Device Information:

Medela Swing Breast Pump (K053052); Medela AG

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

6. Indications for Use:

The Electric Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The electric breast pump is intended for a single user.

7. Device Description:

The Electric Breast Pump is a personal use electric breast pump capable of single pumping. The device is electrically powered from either internal batteries or an external AC powered supply and is provided non-sterile.

The Electric Breast Pump consists of the motor, breast shields, tubing, bottle and valve. The materials used are silicone (breast shield) and polypropylene (Pump body and bottle).

The electric breast pump's drive unit employs a diaphragm-type vacuum pump, powered by a DC-motor, supervised by a microcontroller. The microcontroller provides control over motor speed (vacuum creation) and solenoid (vacuum release).

The device has two modes of operation:

- Stimulation mode: Suction patterns with fast cycles and low vacuum to start milk flowing
- Expression mode: Suction patterns with slow cycles and high vacuum to express more milk gently and efficiently.

8. Predicate Device Comparison:

	Subject Device K172989	**Predicate device K053052**	**Comparison**
Indication for use	A powered breast pump to be used by lactating women to express and collect milk from their breasts.	A powered breast pump to be used by lactating women to express and collect milk from their breasts.	Identical
Patient Population	Lactating women	Lactating women	Identical
Environment of Use	Home	Home or Hospital	Similar
Single/double pump	Single pump	Single pump	Identical
Re-usable	Yes	Yes	Identical
Direct user contact	Yes	Yes	Identical
Adjustable suction levels	Yes	Yes	Identical

Visual indicator	LCD Screen	LED	Similar
Vacuum range (mmHg)	-60~-250mmHg	-50~-250mmHg	Similar
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor	Identical
Breastshield size	24mm or 27mm	21mm,24mm,27mm,30mm or 36mm	Similar.
Cleaning method for Accessories	Soap and warm water	Soap and warm water	Identical
Battery type	4 AA batteries or Medical AC Adapter (DC6.0V, 1000mA)	4 AA batteries or AC Adapter (DC4.8V, 1.2A)	Similar
Battery use life	Approx.1.5h for pumping time	Approx.1.5h for pumping time	Identical
Low battery indicator	Yes	Yes	Identical
Automatic Power-Off	Yes	Yes	Identical

The Electric Breast Pump has the same intended use but minor differences in technological characteristics compared to the predicate device. These minor differences in technological characteristics do not raise different questions of safety and effectiveness.

9. Performance data

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

Performance testing was conducted to validate and verify that the Electric Breast Pump met all requirements of the applicable standards, including electrical safety, EMC, and biocompatibility. Results of these tests demonstrate compliance to the following standards:

Electrical Safety and performance requirements:

- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment

Home-used medical equipment requirements and environmental test:

- IEC 60601-1-11:2015 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 requirements:

- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Biocompatibility Evaluation for patient contacting components:

- Cytotoxicity - ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- Sensitization - ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

- Irritation - ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Software Validation

The software/firmware verification and validation was provided in accordance with the FDA Guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

Bench Performance Testing

The following bench testing was completed on the subject device:

- Vacuum pressure range (suction)
- Maximum vacuum pressure
- Backflow-leakage testing
- Battery life testing

10. Conclusions:

The performance testing provided is sufficient to support substantial equivalence determination. Based on the information provided in this submission, the Joytech Electric Breast Pump is as safe and effective as the predicate Medela Swing Breast Pump.