December 19, 2024

Joytech Healthcare Co., Ltd.
Yanyan Zhang
Regulation Affair
No.365, Wuzhou Road
Hangzhou, Zhejiang 311100
CHINA

Re: K241322
Trade/Device Name: Electric Breast Pump (LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: Class II
Product Code: HGX
Dated: November 21, 2024
Received: November 21, 2024

Dear Yanyan Zhang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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)*
K241322

Device Name
Electric Breast Pump (Model LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010)

Indications for Use *(Describe)*
The Electric Breast Pump (Model LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010) 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.

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510(k) Summary

1. Submitter Information

Applicant: JOYTECH Healthcare Co.,Ltd.
Address: No.365, Wuzhou Road, Hangzhou, Zhejiang 311100,China

2. Correspondent Information

Contact: Yanyan Zhang
Regulation Affairs
Email: zhangyy@sejoy.com
Phone: 86 (571) 8195-7767

3. Date prepared: December 12, 2024

4. Device Information

Device Name:	Electric Breast Pump (LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010)
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:	Electric Breast Pump Model: YM-8166
510(k) Number:	K232466
Manufacturer:	Guangdong Youmeng Electrical Technology Co., Ltd.

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

6. Device Description

The Electric Breast Pump (LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010) is an electrically powered breast pump to be used in a home environment by a single user. The device is provided non-sterile and can be used on one breast (single pumping) or on both breasts at the same time (double pumping).

The subject devices are capable of expression, stimulation, and the hybrid 'bionic' and 'variable frequency' modes. Stimulation mode is associated with six suction levels, and expression, bionic, and variable frequency modes are associated with nine suction levels. The subject devices feature various combinations of on/off buttons, level up/down buttons, mode selection buttons, suction level/time indicators, battery visual indicator display, and mode displays. The LD-208L, LD-3010L, and LD-2010L pumps are powered by internal, non-replaceable, rechargeable lithium-ion batteries which are charged using the included AC power supply and cable. The LD-2010 and LD-3010 are powered by alkaline batteries or AC power.

The breast pumps use cyclic negative pressure (suction) to mimic the suckling patterns of a feeding infant. A DC motor drives a membrane vacuum pump to generate the suction required to stimulate and express breast milk. The timing of this pattern is dependent upon the suction/speed settings selected by the user and is pre-

programmed in the devices. The devices are capable of producing peak suction levels between -40 and -290 mmHg at speeds between 20 and 120 cycles per minute. The subject device ensures backflow protection between the breast shield and the electronic components via a physical barrier (silicone diaphragm) mechanism.

All other components (i.e., motor unit) of the subject device are not in contact with the breast. All milk contacting components are compliant with 21 CFR 177.

7. Indications for Use

The Electric Breast Pump (Model LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010) 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.

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 (Model LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010) K241322 Subject Device	**Electric Breast Pump Model: YM-8166 K232466 Predicate Device**	**Comparison**
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	Lactating Women	Same
Indications for Use	The Electric Breast Pump (Model LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010) 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.	The Electric Breast Pump Model: YM-8166 is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user	Similar
Single/double pump	Single or double	Single or double	Same
Media separation (backflow protection)	Yes	Yes	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Expression pattern	2-Phase	2-Phase	Same
Power supply	LD-3010L,LD-2010L:	USB connector (Only	Different

	In:100 - 240 VAC 50/60 Hz 0.25A Mains Out: 5VDC, 1.0A Batt Out: 3.7VDC 2000mAh LD-3010,LD-2010: In:100 – 240 VAC 50/60 Hz 0.25A Mains Out: 5VDC, 1.0A Batt Out: 4 AA batteries LD-208L: In:100 - 240 VAC 50/60 Hz 0.25A Mains Out: 5VDC, 1.0A(Only for charging) Batt Out: 3.7VDC 1200mAh	for charging) by DC 5 V, 2 A	
Suction levels (expression)	50-290 ± 30 mmHg	85-280 ± 20 mmHg	Different
Suction levels (stimulation)	40-100 ± 30 mmHg	60-165 ± 20 mmHg	Different
Cycles per minute (expression)	20-65 ± 5 cpm	24-84 ± 5 cpm	Different
Cycles per minute (stimulation)	80-120 ± 5 cpm	39-123 ± 5 cpm	Different
Suction levels	9 expression, bionic, variable frequency; 6 stimulation	16 levels	Different
Available modes	Stimulate mode,Expression mode, Bionic sucking mode,Variable frequency pumping mode	Stimulation Mode, Expression Mode, Pseudo-true Expression Mode, Array Mode, and Single/ double Pumping Mode	Different
User Interface	On-Off switch, mode change button, vacuum adjustment buttons, LED	Power button; Mode adjustment button ; Vacuum level increase/decrease button; Night light button (optional) ; Single/ double pumping change button	Similar
Adjustable Suction Levels	Yes	Yes	Same
Mobile Application	No	No	Same
Design	LD-3010L, LD-3010, LD-2010L, LD-2010: Tabletop LD-208L: Wearable	Not specified	--

The indications for use of the subject and predicate device are identical and they have the same intended use – the expression and collection of breast milk.

The subject and predicate devices have similar technological features, user interface and single/double pumping operation. However, as shown in the table above, there are technological differences between the subject and predicate device, including different overall vacuum pressure specifications/cycle speeds, available pumping modes, etc. However, the different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including Skin Irritation Testing, Cytotoxicity, and Skin Sensitization testing were performed in accordance with the 2023 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"* as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Skin Sensitization (ISO 10993-10:2021)
- Skin Irritation (ISO 10993-23:2021)

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

Electrical Safety

Testing was conducted in accordance with IEC 60601-1 Edition 3.2 2020-08 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance), 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, IEC 60086-5:2016 Primary batteries – Part 5: Safety of batteries with aqueous electrolyte, and IEC 60601-1-11 Edition 3.1 2020-07 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+A1: 2020 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 at the Basic Documentation level as recommended in the 2023 FDA guidance document "*Content of Premarket Submissions for Device Software Functions.*"

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.

- 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 results of the performance testing described above demonstrate that the Electric Breast Pump (LD-208L, LD-3010L, LD-2010L, LD-3010, LD-2010) is as safe and effective as the predicate device and supports a determination of substantial equivalence.