June 27, 2022

Shenzhen Lutejiacheng Technology Co., Ltd.
℅ Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1309, Dongfang Building,
1500# Century Avenue
Shanghai, 200122
China

Re: K220309
Trade/Device Name: Wearable Breast Pump (Model S10)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 26, 2022
Received: May 26, 2022

Dear Eva Li:

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,

For
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)*
K220309

Device Name
Wearable Breast Pump (Model S10)

Indications for Use *(Describe)*
The Wearable Breast Pump (Model S10) is intended to express milk from lactating women in order to collect milk from their breasts. The 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 – K220309

1. Submitter Information

Applicant: Shenzhen Lutejiacheng Technology Co., Ltd.
Contact: Johnny Dai
Phone: 0086-755-8486 1362
Email: yanhe.dai@rootglobal.net
Address: Rm 903 Jiangnan Bldg, No l Bantian Ave.South, Ma'antang,Bantian St. Shenzhen .

2. Correspondent Information

Contact: Eva Li
Phone: + 86 (215) 881-7802
Email: eatereva@hotmail.com
Address: Shanghai SUNGO Management Consulting Co., Ltd. Room 1401, Dongfang Building, 1500# Century Ave, Shanghai, 200122 CHN

3. Date prepared: June 24, 2022

4. Device Information

Device Name:	Wearable Breast Pump (Model S10)
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:	Youha electric breast pump
510(k) Number:	K163136
Manufacturer:	Ningbo Youhe Electrical Appliance Technology Co., Ltd.

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

6. Device Description

The Wearable Breast Pump (Model S10), is an electrically powered wearable single breast pump consisting of the following key components: a flange, linker, silicone diaphragm, pump motor, type-C USB cable, valve, and milk collector. It is designed to work in the user's bra and has a rechargeable battery so it can be used hands-free without any external power cords. The motor unit includes a press-button user interface, pump body, and LED display. Pumping can be performed on one breast (single pumping). The user interface allows the user to switch from stimulation to expression mode and control the vacuum levels within those modes. Both stimulation and expression mode consist of 9 vacuum levels. The S10 model is capable of providing vacuum levels from 45-112 mmHg with cycling rates from 49-100 cycles per minute in stimulation mode and vacuum levels from 133-225 mmHg with cycling rates from 20-57 cycles per minute in expression mode. The Wearable Breast Pump (Model S10) is charged with a 5 V DC adaptor and powered by an internal rechargeable lithium-ion polymer battery. The motor unit operates on embedded software. Software updates

by end-users are not supported. The subject device is for repeated use by a single user in a home environment. The device is provided not sterile.

The breast pump expresses by creating a seal around the nipple using the flange and applying and releasing suction to the nipple. The milk is collected in a milk collection container. To prevent milk from flowing into the vacuum system, a backflow protection membrane physically separates the milk-contacting pathway from the vacuum system.

The motor unit operates on a rechargeable battery and does not function when charging. The rechargeable battery can be charged from the external USB adapter.

The subject device components are made of the following materials:

- Motor unit: acrylonitrile-butadiene-styrene (ABS) plastic
- Flange, tube, valve, diaphragm: Silicone
- Linker, milk collection container: Polypropylene

All milk contacting components are compliant with 21 CFR 174-179.

7. Indications for Use

The Wearable Breast Pump (Model S10) is intended to express milk from lactating women in order to collect milk from their breasts. The device 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

	Wearable Breast Pump (Model S10) K220309 Subject Device	**Youha electric breast pump K163136 Predicate Device**	**Comparison**
Product Name	Wearable Breast Pump (Model S10)	Youha electric breast pump	**N/A**
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 Wearable Breast Pump (Model S10) is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.	The Youha electric breast pump is intended to be used by lactating women to express and collect milk from their breasts. The device is intended for a single user.	The indications for use statements for the subject and predicate devices are not identical, but both devices have the same intended use (i.e., express and collect milk from the breasts of lactating women).
Pump Options	Single	Single or Double	**Different:** The difference in single and double pumping between the subject and predicate devices does not raise different questions of safety and effectiveness.
Cycling control	Microcontroller	Microcontroller	**Same**

mechanism			
Backflow Protection	Yes	Yes	**Same**
Suction Modes	Stimulation Mode and Expression Mode	Stimulation Mode and Low/High Expression Mode	**Different:** The differences in available modes do not raise different questions of safety and effectiveness
Suction levels	9	6 – 10 depending on model	**Different:** The differences in suction levels for each mode do not raise different questions of safety and effectiveness
Adjustable suction levels	Yes	Yes	**Same**
Flange Size	24 mm and 27 mm	Not Provided	**Different:** Differences in flange sizes do not raise different questions of safety and effectiveness.
Vacuum range: Stimulation	-45 to -112 (±5) mmHg	-34 to -190 mmHg depending on model	**Different:** The difference in specification does not raise different questions of safety and effectiveness.
Vacuum range: Expression	-133 to -225 (±5) mmHg	Low: -75 to -250 mmHg High: -120 to -280 mmHg depending on model	**Different:** The difference in specification does not raise different questions of safety and effectiveness.
Cycle Speed: Stimulation	49 to 100 (±2) cycles/minute	71 to 113 cycles/minute depending on model	**Different:** The difference in specification does not raise different questions of safety and effectiveness.
Cycle Speed: Expression	20 to 57 (±2) cycles/minute	Low: 36 to 69 cycles/minute High: 16 to 57 cycles/minute depending on model	**Different:** The difference in specification does not raise different questions of safety and effectiveness.
Controls	On/Off button; Mode selection Increase/decrease vacuum button;	Front panel keypad for controls	**Similar:** The subject and predicate have similar controls. Differences in controls do not raise different questions of safety and effectiveness.
Power Supply	Li-Ion Battery	Li-Ion Battery and AC power	**Different:** The difference in power source does not raise different questions of safety and effectiveness.
Indicators	Yes, LED	Yes, LCD	**Similar**

The indications for use of the subject and predicate device are not identical in wording. However, the intended use for the subject and predicate devices are the same (i.e., express and collect milk from the breasts of lactating women).

The subject and predicate device have different technological features as noted in the table above. These technological differences do not raise different questions of safety or effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing was conducted in accordance with the 2020 FDA guidance *Use of*

International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process." Testing included:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)

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

Electrical Safety
Testing was conducted in accordance with:

- AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-11:2015 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.
- 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

Electromagnetic Compatibility
Testing was conducted in accordance with IEC 60601-1-2:2014 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 as recommended in the 2005 FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Performance Testing
Performance testing was conducted to demonstrate pump performance met established specifications in the following areas:

- 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 device pump.
- 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.
- Battery charging testing to demonstrate the duration of time needed to fully recharge the battery.

10. Conclusion

The subject and predicate devices have the same intended use and the technological differences do not raise different questions of safety or effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.