December 9, 2022

Mayborn (UK) Limited
% Shelley Li
Offical Correspondent
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 1308, Baohua International Plaza,
555 West Guangzhong Road
Shanghai, 200072
China

Re: K221598
Trade/Device Name: Wearable Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: October 31, 2022
Received: October 31, 2022

Dear Shelley 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,

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)*
K221598

Device Name
Wearable Breast Pump

Indications for Use *(Describe)*
The Wearable Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. It 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 – K221598

I. Submitter

MAYBORN (UK) LIMITED
MAYBORN HOUSE BALLIOL BUSINESS PARK, NEWCASTLE UPON TYNE NE12 8EW UNITED KINGDOM

Manufacturer:

Jiangsu Xinbei Electrical Appliances Co., Ltd.
No. 115 Xinjin Road, Xinwu District, Wuxi City, Jiangsu Province

Contact person

Sean Neasham
Group Quality Manager
Phone: +44 191 250 4509
E-mail: sneasham@mayborngroup.com

Date of preparation: December 7, 2022

II. Proposed Device

Trade Name:	Wearable Breast Pump
Common name:	Powered breast pump
Regulation Number:	21 CFR 884.5160
Regulation Name	Powered breast pump
Regulatory Class:	Class II
Product code:	HGX (Pump, Breast, Powered)
Review Panel	Obstetrics/Gynecology

III. Predicate Device

510(k) Number:	K181863
Trade name:	Elvie Pump
Common name:	Powered breast pump
Classification:	Class II
Product Code:	HGX
Manufacturer	Jabil Circuit (Shanghai) LTD

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

IV. Device description

The Wearable Breast Pump (model: 1203) is an electric breast pump system comprised of a single or double portable unit that integrates the pump body and milk collection bottle. It consists of a pump (motor unit) and includes a breast shield, bottle, seal, valve, spout, and bra adjuster. All components (minus the pump) are reusable and may be manually cleaned.

The Wearable Breast Pump includes rotary electric pump technology which generates negative pressure on the nipple to express milk, which is collected in the integrated milk collection bottle. It is designed to work in the user's nursing bra and has a rechargeable battery so it can be used hands-free without external power cords or milk collection tubes.

The Wearable Breast Pump is a battery-powered electro-mechanical device that can be controlled through the physical interface on the device or through a mobile companion app, which also provides real-time milk monitoring, pump battery life, pumping time elapsed, and pumping history information.

All milk contacting components are constructed out of food grade materials that are compliant with 21 CFR 174-179..

V. Indications for use

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

VI. Comparison of technological characteristics with the predicate device

The intended use and key technological characteristics of the subject and predicate device are compared in the table below.

Item	Proposed device	Predicate device (K181863)	Comparison
Trade name	Wearable Breast Pump	Elvie Pump	NA
Product Code	HGX	HGX	Same
Regulation No.	21 CFR 884.5160	21 CFR 884.5160	Same
Classification	Class II	Class II	Same
Indications for use	The Wearable Breast Pump is a powered breast pump to be used by lactating	The Elvie Pump is a powered breast pump to be used by lactating women to	Same

	women to express and collect milk from their breasts. It is intended for a single user.	express and collect milk from their breasts. The Elvie Pump is intended for a single user.	
Intended Use	Express milk from breast	Express milk from breast	Same
Environments of Use	Home	Home	Same
Single User device	Yes	Yes	Same
Single / Double Pumping	Both	Both	Same
Patient Population	Lactating women	Lactating women	Same
Over the Counter	Yes	Yes	Same
Power Source	Power adapter (battery charger) and Li-Ion Battery	USB cable (battery charger) and Li-Ion Battery	Similar
Adjustable Suction Levels	Yes	Yes	Same
Backflow Protection	Yes	Yes	Same
Suction Strength	12-253 mmHg	40-220 mmHg	Different
Maximum Suction Strength	253 mmHg	220 mmHg	Different
Expression levels	8	7	Different
Pump type	Rotary Electric Pump	Piezoelectric Pump	Same
Two-phase Expression	Yes	Yes	Same

User Controls	On pump body and/or through app	On pump body and/or through app	Same
Control Mechanism	Microcontroller	Microcontroller	Same
Mobile App	Yes	Yes	Same

The subject and predicate device have identical indications for use statements and have the same intended use. The subject and predicate device have different technological characteristics, including different pump types, suction specifications, maximum suction pressure specifications, and power sources. However, the different technological characteristics do not raise different safety and effectiveness questions.

VII. Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications and that the subject device is substantially equivalent to the predicate device, as follows.

a) Electrical Safety, Electromagnetic Compatibility, and Wireless Technology

- IEC 60601-1: 2005+corr.1:2006+Corr.2.2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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
- IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 (second edition) 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 environments

- IEC 62133:2012 – 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
- Documentation provided in accordance with the FDA Guidance document, "Radio Frequency Wireless Technology in Medical Devices" dated August 14, 2013.

b) Biocompatibility

Biocompatibility testing in accordance with the FDA guidance "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" dated September 4, 2020. Testing included the following assessments:

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

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

c) Software Validation

Software validation testing was conducted for a "moderate level of concern" as recommended in the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

d) Performance Testing

- Vacuum pressure and cycle rate testing was conducted at all settings and demonstrated that the device met its specifications.
- Backflow testing was conducted to demonstrate that liquid does not backflow into the tubing/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.

IX. Conclusion

The performance testing described above demonstrates that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device.