June 26, 2026

Shenzhen Changkun Technology Co., Ltd.
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Mgmt Consulting Co., Ltd
Room 1509, Jingting Building, Dongzhou Community
Guangming Street, Guangming District
Shenzhen, Guangdong 518122
CHINA

Re: K250070
Trade/Device Name: Electric Breast Pump (MY-375,MY-376,MY-378, MY-379,MY-380,V3)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: December 8, 2025
Received: December 8, 2025

Dear Reanny Wang:

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: The Center for Devices and Radiological Health (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, he Food and Drug Administration (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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250070

Device Name
Electric Breast Pump (MY-375,MY-376,MY-378,MY-379,MY-380,V3)

Indications for Use *(Describe)*
The Electric Breast Pump (MY-375,MY-376,MY-378,MY-379,MY-380,V3) is intended to be used by lactating women to express and 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-K250070

1. Submitter Information

Company Name: Shenzhen Changkun Technology Co., Ltd.

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Contact Person: Wang Qingpeng

Contact Title: General Manager

Contact Email: 605984618@qq.com

2. Consultant's Information

Company Name: Shenzhen Reanny Medical Devices Management Consulting Co.,Ltd.

Street Address: Room 1509, Jingting Building, Dongzhou Community, Guangming Street, Guangming District, Shenzhen, China

Contact Person: Reanny Wang

Contact Email: reanny@reanny.com

3.Date prepared: June 24, 2026

4. Subject Device Information

Device Trade Name: Electric Breast Pump (MY-375, MY-376, MY-378, MY-379, MY-380, V3)

Common Name: Powered Breast Pump

Regulation Number: 21 CFR 884.5160

Regulation Name: Powered Breast Pump

Product Code: HGX (Pump, Breast, Powered)

Classification Panel: Obstetrics/Gynecology

Regulatory Class: Class II

5. Predicate Device Information

Device Name: Electric breast pump (Model MY-373)

510(k) Number: K231595

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

6. Device Description

The Electric Breast Pump is a wearable powered breast pump intended to be used by lactating women to express and collect milk from their breast. The breast pump stimulates lactation and extracts milk from the breasts by creating a seal around the nipple and applying and releasing suction to the breast. The milk is collected in a milk collection container. The device is not sterile and is meant for repeated use by a single user.

The device uses a diaphragm-type vacuum pump controlled by a microprocessor. The microprocessor provides control over vacuum pressure and cycle speed. The device provides for single suction. The user interface consists of buttons and LED display allowing the user to switch between modes and levels of vacuum pressure and displaying the information of current working mode, operating time and battery status.

The device includes six models - MY-375, MY-376, MY-378, MY-379, MY-380, V3, and these models have same working principle and similar technological characteristics. These models differ in terms of their appearance, milk collection set components, and user interface. All models include four modes of operation Massage mode, Pumping mode, Inverter Pumping mode, and Automatic mode. Massage mode, Pumping mode, and Automatic mode have twelve suction levels each, while the Inverter Pumping mode has six distinct suction levels.

To prevent milk from flowing into the vacuum system, the milk collection set includes a diaphragm that physically separates the milk-contacting pathway from the vacuum system. The valve between the milk collector and linker prevents the milk in the bottle from flowing back to the Linker during suction.

The motor unit operates on a 3.7V rechargeable lithium battery. The rechargeable battery can be charged from the external power adapter (not included in this device) through the provided charging cable. Milk contacting components of the device are compliant with 21 CFR 177.

7. Indications for Use

The Electric Breast Pump (MY-375,MY-376,MY-378,MY-379,MY-380,V3) is intended to be used by lactating women to express and 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: Comparison Table for Subject and Predicate Devices

Device	Subject device (K250070)		Predicate device (K231595)	Comparison
Product name	Electric Breast Pump (MY-375,MY-376, MY-378, MY-379, MY-380, V3)		Electric breast pump (Model:MY-373)	NA
Product Code	HGX		HGX	Same
Regulation Number	21 CFR 884.5160		21 CFR 884.5160	Same
Regulatory Class	Class II		Class II	Same
Single user	Yes		Yes	Same
Patient Population	Lactating Women		Lactating Women	Same
Use Environment	Home Healthcare Environment		Home Healthcare Environment	Same
Indications for Use (IFU)	The Electric Breast Pump (MY-375,MY-376,MY-378,MY-379,MY-380,V3) 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 Electric Breast Pump 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
OTC or Rx	OTC		OTC	Same
Pump Options	Single pumping		Single pumping	Same
Provided non-sterile	Yes		Yes	Same
Media Separation (Backflow Protection)	Yes		Yes	Same
Suction Modes	Massage Mode Pumping Mode Inverter pumping mode Automatic mode		Lactation Mode Pumping mode Inverter pumping mode Sucking mode	Similar
Adjustable suction levels	Yes		Yes	Same
Vacuum range(mmHg)	Massage mode: 15 to 140 Pumping mode: 68 to 292 Inverter Pumping mode: 20/150 to 80/150 Automatic mode: 23 to 287		Lactation mode: 30 to 225 Pumping mode: 80 to 292 Inverter Pumping mode: 60 to 282 Sucking mode: 55 to 270	Different
Cycle Speed (cycles/minute)	Massage mode: 87 to 115 Pumping mode: 33 to 105 Inverter Pumping mode: 87 to 115 Automatic mode: 33 to 113		Lactation mode: 36 to 85 Pumping mode:26 to 56 Inverter Pumping mode:32 to 78 Sucking mode: 24 to 47	Different
Maximum Suction	297 mm Hg		297 mmHg	Same
Controls	MY-375, MY-378, V3	MY-376, MY-379, MY-380	Power button, Mode button, Gear minus button, Gear plus button	Similar

Device	Subject device (K250070)		Predicate device (K231595)	Comparison
	On/Off/Mode button, Gear Shift(+), Gear Shift(-)	Power/Pause button, Mode button, Gear Shift(+), Gear Shift(-)		
Indicators	LED indicators		LED indicators	Same
Power Supply	DC 5V 1A 3.7V 1200mAh Rechargeable Li-ion battery		DC 5V 1A 3.7V 1200mAh Rechargeable Li-ion battery	same
Pump type	Diaphragm		Diaphragm	Same
Materials	Milk collector: PP (Polypropylene), Silicone shield: Silicone, Host: ABS		Milk collector: PP (Polypropylene), Silicone shield: Silicone, Host: ABS	Same

The subject and predicate device have similar Indications for Use statements and same intended use (i.e., for the collection of breast milk from the breasts of lactating women). As shown in the table above, there are technological differences between the subject and predicate device, including different vacuum/cycle specifications and available suction levels in each mode. 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

Non-clinical tests were conducted to verify that the subject devices met all design specifications to be considered substantially equivalent to the predicate device:

9.1. Biocompatibility Testing

The biocompatibility evaluation for the patient-contacting components was leveraged from the predicate device and was 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””.

9.2. Electrical Safety and EMC

Electrical safety and EMC testing was performed per the following standards:

- 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

- IEC 60601-1:2005/AMD2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, with US National deviations
- IEC 60601-1-11:2015/AMD1:2020, Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment, with US National deviations
- 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

9.3. Software Verification and Validation

Software verification and validation consistent with basic documentation level per the 2023 FDA guidance document “Content of Premarket Submissions for Device Software Functions”. System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met, and all software hazards have been mitigated to acceptable risk levels.

9.4. Non-Clinical Performance Testing

Additional non-clinical performance tests were conducted to demonstrate that the device meets its design requirements and performs as intended throughout its proposed service-life:

- Vacuum pressure and cycle frequency test for all modes and levels of device operation.
- Battery capacity and battery indicator accuracy test to demonstrate that the battery and battery indicator function as intended during its stated use-life.
- Backflow protection testing to ensure no liquid will backflow into the air inlet
- Use-life testing

The subject device met the pre-defined acceptance criteria for all the above tests.

10. Conclusion

The results of the performance testing described above demonstrate that Electric Breast Pump (MY-375, MY-376, MY-378, MY-379, MY-380, V3) is as safe and effective as the

predicate device and supports a determination of substantial equivalence to the predicate device.