June 25, 2026

Shenzhen Qinyi Electronic Technology Co., Ltd.
% Amos Zou
Medical Device Consultant
Huide Medical Technology Service Group Co., Ltd.
Rm. 703, Bldg. 16, S. Bank Plz., Exhibition Bay
Zhancheng Community, Fuhai St., Bao'An District,
Shenzhen, 518103
CHINA

Re: K261025
Trade/Device Name: Wearable Breast Pump (QY-101, QY-102, QY-108)
Regulation Number: 21 CFR 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: March 28, 2026
Received: March 30, 2026

Dear Amos Zou:

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, the 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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)*
K261025

Device Name
Wearable Breast Pump (QY-101, QY-102, QY-108)

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

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

K261025

1. Submitter of 510(K):

Sponsor:

Company Name:	Shenzhen Qinyi Electronic Science & Technology Co., Ltd.
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Application Correspondent:

Company Name:	Huide Medical Technology Service Group Co., Ltd
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Contact person:	Mr. Amos Zou
TEL:	+86-15015249549
E-mail:	546977693@qq.com

Date of Preparation: June 24, 2026

2. Device Information

Device Trade Name:	Wearable Breast Pump (QY-101, QY-102, QY-108)
Models:	QY-101, QY-102, QY-108
Common Name:	Powered breast pump
Product Code:	HGX(pump, breast, powered)
Regulation number	21 CFR 884.5160
Regulation Name	Powered breast pump
Regulatory Class	II

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K243508	Wearable Breast Pump (Model S12A) ;	Shenzhen TPH Technology Co., Ltd.

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

4. Device Description:

This Wearable Breast Pump (QY-101, QY-102, QY-108) is a powered breast pump for use by nursing mothers to extract and collect breast milk from their breasts.

The equipment works based on vacuum and siphon principles. A built-in motor drives the diaphragm pump to generate negative pressure, which acts on the breast through the silicone shield to remove milk. The device contains a backflow protection membrane that physically isolates the milk flow channel from the vacuum system.

The device is an integrated wearable design, consisting of a pump main unit, a silicone shield, an anti-backflow diaphragm, a valve, a connector and a milk storage bottle. All parts that come into contact with milk are made of materials that comply with 21 CFR 177.

The device is powered by a rechargeable lithium battery and provides massage, sucking and other modes, and the user can control and adjust it through a button interface. The equipment is provided non-sterile and relevant parts need to be cleaned after use.

5. Indications for Use

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

6. Comparison of Intended Use and Technical Characteristics with the Predicate Device

The following table compares the intended use and technological characteristics of the subject and predicate device.

Comparison Item	Subject Device	Predicate device
Product Description and Model	Wearable Breast Pump (Models: QY-101,QY-102,QY-108)	Wearable Breast Pump (Model S12A)
510(k) No.:	K251025	K243508

Indications for Use	The Wearable Breast Pump is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts.	The Wearable Breast Pump (Model S12A) is a powered breast pump intended to be used by lactating women to express and collect milk from their breasts. It is intended for a single user.
Design Type	Wearable, electric, single-user	Wearable, electric, single-user
Single/Dual Pump Use	Single pump (dual pump possible with two units)	Single or dual pump (two units required)
Backflow Protection	Yes	Yes
Control Mechanism	Microprocessor-controlled (inferred by product type)	Microprocessor-controlled
Power Source	1200 mAh Li-ion battery, charged by adapter (not for use during charging)	Li-ion battery, 5V DC adapter charging (not for use during charging)
Working Modes	Massage, Suction, Mixed	Stimulation, Expression, Auto
Vacuum Pressure Range	Massage: -30 to -70 mmHg; Suction: -50 to -250 mmHg; Mixed: -30 to -200 mmHg	Stimulation: -30 to -160 mmHg; Expression: -120 to -245 mmHg; Auto: -30 to -245 mmHg
Cycle Rate Range	Massage: 86–113 cycles/min; Suction: 27–104 cycles/min; Mixed: 84–108 cycles/min	Stimulation: 74–134 cycles/min; Expression: 29–92 cycles/min; Auto: 29–128 cycles/min
Suction Levels	12 levels (QY-108) 9 levels (QY-101,QY-102)	12 levels
User Interface	LED battery indicator / control panel display	LED status display

Key Materials	Biocompatible materials: polypropylene, silicone	Collection bottle/connector: polypropylene; flange/valve/diaphragm: silicone
Electrical Safety	Complies with IEC 60601-1 and other standards	Complies with IEC 60601-1 and other standards
Biocompatibility	Assessed per ISO 10993 series	Assessed per ISO 10993 series

The subject Wearable Breast Pump (Models QY-101, QY-102, and QY-108) and the predicate Wearable Breast Pump (Model S12A, K243508) have the same intended use and similar technological characteristics. Both devices are wearable, electrically powered, single-user breast pumps intended for lactating women to express and collect breast milk and incorporate adjustable vacuum levels, multiple pumping modes, rechargeable lithium-ion batteries, and backflow protection mechanisms.

Differences between the devices include the specific operating modes, vacuum pressure ranges, cycle rate ranges, suction level configurations, and user interface features. These differences do not alter the intended use or fundamental principles of operation. Performance testing, including bench, electrical safety, EMC, software, and biocompatibility testing, demonstrated that the subject device performs as intended and supports a finding of substantial equivalence to the predicate device.

7. Summary of Non-Clinical Performance Testing

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

7.1 Biocompatibility

The biocompatibility evaluation for the subject device was conducted in accordance with Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".” The following endpoints were assessed:

1) ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2) ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
3) ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

The results of these tests demonstrated that the patient-contacting components of the subject device are non-cytotoxic, non-sensitizing, and non-irritating.

7.2 Electrical Safety and electromagnetic compatibility

The subject device has been tested in accordance with and found to comply with the following standards:

1) IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2) IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3) IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION 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.
4) IEC TR 60601-4-2:2016, Medical electrical equipment- Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.
5) IEC 62133-2 Edition 1.0 2017-02 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

7.3 Software

Software was evaluated as recommended in the 2023 FDA guidance document, *Content of Premarket Submissions for Software Functions* consistent with the "Basic Documentation Level."

7.5. 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.

9.Conclusions:

The results of the performance testing described above demonstrate that the Wearable Breast Pump (Models QY-101, QY-102, QY-108) are as safe and effective as the predicate device and supports a determination of substantial equivalence.