May 30, 2025

Ningbo Youhe Electrical Appliance Technology Co.,Ltd.
℅ Daniel Qiu
Project Manager
Shanghai Qisheng Business Consulting Co., Ltd.
Room 1301, Building 46, Jing Gu Zhong Rd. 58
Minhang District
Shanghai, 200240
CHINA

Re: K242725
Trade/Device Name: Youha electric breast pumps (The INs, The INs Gen2, The INs NEXT, and P3) and BEBEBAO electric breast pump (P1s)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: May 1, 2025

Dear Daniel Qiu:

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
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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)*
K242725

Device Name
Youha electric breast pumps (The INs, The INs Gen2, The INs NEXT, and P3) and BEBEBAO electric breast pump (P1s)

Indications for Use *(Describe)*
The Youha electric breast pumps (The INs, The INs Gen2, The INs NEXT, and P3) and BEBEBAO electric breast pump (P1s) are powered breast pumps intended to be used by lactating women to express and collect milk from their breasts. They are 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.

***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 – K242725

## 1. Submitter Information

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## 2. Correspondent Information

Contact: Daniel Qiu
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## 3. Date prepared: May 29, 2025

## 4. Device Information

| | |
|---|---|
| Device Name: | Youha electric breast pumps (The INs, The INs Gen2, The INs NEXT, and P3) and BEBEBAO electric breast pump (P1s) |
| 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: | Elvie Stride |
| 510(k) Number: | K210936 |
| Manufacturer: | Chiaro Technology Limited. |

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

## 6. Device Description

The subject devices are wearable-style breast pumps designed for lactating women to express and collect milk from the breast. They are electrically powered, software controlled, digital pumps for a single user. The subject devices include The INs, The INs Gen 2, The INs NEXT, P1s, and P3 models, which are capable of expression, massage, and mixed modes with ten associated suction levels for each. All five models have a single pumping configuration and can be operated in 'normal' or 'quiet' modes.

Massage, expression, and mixed pumping modes consist of 10 vacuum levels. Each Youha and BEBEBAO electric breast pump model is capable of providing vacuum levels from 40-190 mmHg with cycling rates from 90-110 cycles per minute in massage mode, vacuum levels from 80-280 mmHg with cycling rates from 40-75 cycles per minute in expression mode, and vacuum levels from 80-280 mmHg with cycling rates from 6-46 cycles per minute in mixed mode. The Youha electric breast pump 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 devices do not have wireless capability or other external functionality (i.e., no Bluetooth or mobile application). The subject device is for repeated use by a single user in a home environment. The device is provided not sterile.

The motor unit operates on a rechargeable battery and can function when charging.

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

All other components (i.e., motor unit/housing) of the subject device are not in contact with the breast. All milk contacting components are compliant with 21 CFR 174-179.

## 7. Indications for Use

The Youha electric breast pumps (The INs, The INs Gen2, The INs NEXT, and P3) and BEBEBAO electric breast pump (P1s) are powered breast pumps intended to be used by lactating women to express and collect milk from their breasts. They are 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**

| | **Youha electric breast pumps (The INs, The INs Gen2, The INs NEXT, and P3) and BEBEBAO electric breast pump (P1s) K242725 Subject Device** | **Elvie Stride K210936 Predicate Device** | **Comparison** |
|---|---|---|---|
| Product Name | **Youha electric breast pumps (The INs, The INs Gen2, The INs NEXT, and P3) and BEBEBAO electric breast pump (P1s)** | **Elvie Stride** | **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 Youha electric breast pumps (The INs, The INs Gen2, The INs NEXT, and P3) and BEBEBAO electric breast pump (P1s) are powered breast pumps intended to be used by lactating | The Elvie Stride is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Elvie Stride is intended for a single user. | **Similar** |

| | | | |
|---|---|---|---|
| | women to express and collect milk from their breasts. They are intended for a single user. | | |
| Pump Options | Single | Single or Double | **Different** |
| Cycling control mechanism | Microcontroller | Microcontroller | **Same** |
| Backflow Protection | Yes | Yes | **Same** |
| Suction Modes | Massage Mode, Expression Mode, Mixed Mode | Stimulation Mode and Expression Mode | **Different** |
| Suction levels | 10 | 10 | **Same** |
| Adjustable suction levels | Yes | Yes | **Same** |
| Vacuum range: Massage | -40 to -190 mmHg | 35-260 mmHg (double)<br>55-300 mmHg (single) | **Different** |
| Vacuum range: Expression | -80 to -280 mmHg | 35-260 mmHg (double)<br>55-300 mmHg (single) | **Different** |
| Vacuum range: Mixed Pumping | -80 to -280 mmHg | N/A | **Different** |
| Cycle Speed: Massage | 90 to 110 cycles/minute | 31 to 83 cycles/min (Stimulation) | **Different** |
| Cycle Speed: Expression | 40 to 75 cycles/minute | 18 to 51 cycles/min (Expression) | **Different** |
| Cycle Speed: Mixed Pumping | 6 to 46 cycles/minute | N/A | **Different** |
| Controls | The INs: one physical button (on/off/mode switch) and two touch keys (increase vacuum and decrease vacuum)<br>The INs Gen 2: three physical button (on/off/mode switch, increase vacuum and decrease vacuum)<br>The INs NEXT: three physical button (on/off/mode switch, increase vacuum and decrease vacuum)<br>P1s: four physical button (on/off, mode switch, increase vacuum and decrease vacuum)<br>P3: three touch keys (on/off/mode switch, increase vacuum and decrease vacuum) | On pump body and/or through app | **Different** |
| Power Supply | USB cable (battery charger) and Li-Ion Battery | USB cable (battery charger) and Li-Ion Battery | **Same** |
| Indicators | The INs: LED light on the on/off button indicates the mode; LED light momentarily displays the remaining time before battery depletion<br>The INs Gen 2: LED light on the on/off button indicates the mode. LED light momentarily displays the remaining time before battery depletion<br>The INs NEXT: LED Screen displays modes, level, timer, minute, battery indicator | Not specified | **Different** |

| | | | |
|---|---|---|---|
| | P1s: LED Screen displays modes, level/timer, minute, battery indicator<br>P3: LED Screen displays modes, level/timer, minute, battery indicator | | |
| Design | Wearable pump | Not specified | **N/A** |

The indications for use of the subject and predicate device are similar, and they have the same intended use (i.e., for collection of breast milk from the breasts of lactating women).

The subject and predicate devices have similar technological features, including wearable operation, power supply, and available vacuum levels. However, as shown in the table above, there are technological differences between the subject and predicate device, including different overall vacuum/cycle specifications, user interface, controls, and available modes. 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 information was provided in accordance with Attachment G of 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."*

**Electrical Safety**
Testing was conducted in accordance with ANSI/AAMI ES60601- 1:2005/A2:2010 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance), IEC 62133-2:2017/A1:2021, 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, and IEC 60601-1-11:2015/A1:2020 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical 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 Youha electric breast pumps (The INs, The INs Gen2, The INs NEXT, and P3) and BEBEBAO electric breast pump (P1s)are as safe and effective as the predicate device and supports a determination of substantial equivalence.