April 14, 2026

Jiangxi AOV Maternity & Baby Products Co., Ltd.
Liben Chen
General Manager
8. Nanhuan Rd., Industrial Park
Guixi, Jiangxi 335400
CHINA

Re: K260239
Trade/Device Name: AOV Wearable Breast Pump
(AOV6853, AOV6860, AOV6861, AOV6862)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: January 16, 2026
Received: January 26, 2026

Dear Liben Chen:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260239

Device Name
AOV Wearable Breast Pump (AOV6853, AOV6860, AOV6861, AOV6862)

Indications for Use *(Describe)*
The AOV Wearable Breast Pump (AOV6853, AOV6860, AOV6861, AOV6862) is intended to be used by lactating women to express 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.

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 – K260239

AOV Wearable Breast Pump

1. Submitter Information:

Sponsor Company Name: Jiangxi AOV Maternity & Baby Products Co., Ltd.
Address: 8. Nanhuan Road, Industrial Park, Guixi, Jiangxi,China
Phone: 086-0701-3330700
Contact Person: Liben Chen
E-mail: sales@aovbaby.com
Date Prepared: April 13, 2026

2. Subject Device Information:

Trade Name:	AOV Wearable Breast Pump (AOV6853, AOV6860, AOV6861, AOV6862)
Common Name:	Powered breast pump
Regulation Name:	Powered breast pump
Regulation Number:	21 CFR 884.5160
Product Code:	HGX (Pump, breast, powered)
Regulatory Class:	Class II

3. Predicate Device Information:

Sponsor:	Zhejiang Carebao Co.,Ltd.
Trade Name:	Wearable Breast Pump (Model: YD-1193, YD-1195, YD-1196, YD-1198, YD-1199; YD-1193S, YD-1195S, YD-1196S, YD-1198S, YD-1199S)
510(k) number:	K222782

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

4. Device Description:

The AOV Wearable Breast Pump is an over-the-counter, non-sterile, single-user, powered breast pump intended to be used by lactating women to express and collect milk from their breasts. The device is intended for daily use in a home environment. The device uses a diaphragm-type vacuum pump driven by software embedded in the device. The
software provides control over vacuum pressure and cycle speed.

The AOV Wearable Breast Pump includes four models: AOV6853, AOV6860, AOV6861, AOV6862. All models operate under single pumping only and have three modes – stimulation, expression, and mixed modes.

The AOV Wearable Breast Pumps has a rechargeable lithium ion battery so it can be used hands-free without any external power cords. The subject device is charged from an external USB adapter and does not function when charging. The user interface includes user-adjustable controls for turning the device on/off, switching between stimulation mode and expression mode and mixed mode, and controlling vacuum level within each of the modes. The subject device expresses milk by creating a seal around the nipple using the flange and applying and releasing suction to the nipple. The milk is collected in the milk collector. To prevent milk from flowing into the vacuum system, a backflow protection diaphragm physically separates the milk-contacting pathway from the vacuum system.

5. Intended Use / Indications for Use

The AOV Wearable Breast Pump (AOV6853, AOV6860, AOV6861, AOV6862) is intended to be used by lactating women to express milk from their breasts. The device is intended for a single user.

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

A comparison of intended use and key technological characteristics between the subject devices and predicate device is listed below:

Device	Subject device	Predicate device
Manufacturer	AOJ HEALTH Technology Co.,Ltd	Zhejiang Carebao Co.,Ltd.
510(K) number	K260239	K222782
Product name	AOV Wearable Breast Pump (Model:AOV6853, AOV6860, AOV6861, AOV6862)	Wearable Breast Pump (Model:YD-1193,YD-1195,YD-1196,YD-1198,YD-1199; YD-1193S,YD-1195S, YD-1196S,YD-1198S,YD-1199S)
Classification	Class II Device, HGX (21 CFR 884.5160)	Class II Device, HGX (21 CFR 884.5160)
Patient Population	Lactating women	Lactating women
Environment of use	Home Healthcare Environment	Home Healthcare Environment
Indications for Use (IFU)/intended use	The AOV Wearable Breast Pump is intended to be used by lactating women to express milk from their breasts. The device is intended for a single user.	The Wearable 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.
Pump Options	Single pumping	Single pumping
Provided Non-sterile	Yes	Yes
Re-usable	Yes	Yes
Direct user contact	Yes	Yes

Device	Subject device	Predicate device
Backflow Protection	Yes	Yes
Suction Modes	Stimulation mode, Expression mode Mixed mode	Stimulation mode and Expression mode Mixed mode
Suction levels	Stimulation mode: 5 Expression mode: 9 Mixed mode: 9	9
Adjustable suction levels	Yes	Yes
Vacuum range	Stimulation mode: -80mmHg ~ -160 (±10)mmHg Expression mode: -110mmHg ~ -270 (±10)mmHg Mixed mode: -80mmHg ~ -270 (±10)mmHg	**YD-1193,YD -1193S, YD-1195,YD-1195S** Stimulation mode:36 to 241mmHg Expression mode:69 to 282mmHg Mixed mode: 68 to 280mmHg **YD-1196,YD-1198,YD-1199; YD-1196S,YD-1198S,YD-1199S** Stimulation mode:37 to 242mmHg Expression mode: 71 to 282mmHg Mixed mode: 68 to 280mmHg
Cycle Speed	Stimulation mode: 55 ~ 110(±2) cycle/min Expression mode: 25 ~ 62 (±2) cycle/min Mixed mode: 40 ~ 86 (±2) cycle/min	**YD-1193,YD -1193S, YD-1195,YD-1195S** Stimulation mode: 37.5 to 150 cycle/min; Expression mode: 23 to 72 cycle/min Mixed mode:12 to 21 cycle/min **YD-1196,YD-1198,YD-1199; YD-1196S,YD-1198S,YD-1199S** Stimulation mode: 37.5 to 150 cycle/min; Expression mode: 24 to 69 cycle /min Mixed mode:12 to 21 cycle/min

Device	Subject device	Predicate device
Controls	AOV6853: On/Off /Switching Button; Increase/decrease vacuum button; AOV6860, AOV6861, AOV6862: On/Off button; Mode selection; Increase/decrease vacuum button;	On/Off button; Mode selection; Increase/decrease vacuum button;
Power Supply	3.7 V Li-ion Battery	Li-ion Battery(internally powered by 3.7Vdc lithium battery or externally powered by 5Vdc USB.
Indicators	Yes, LED	Yes, LED
Pump type	Diaphragm	Diaphragm
Materials	Milk Collector: Polypropylene (AOV6860 and AOV6862) or Tritan (AOV6853 and AOV6861) Flange: Silicone Pump Outer Housing: ABS	Milk Container: Polypropylene Flange: Silicone Pump Outer Housing: Acrylonitrile Butadiene Styrene (ABS) plastic

The AOV Wearable Breast Pump has the same intended use as the predicate device – to express and collect milk from lactating women. The subject and predicate device have different technological characteristics, including different suction modes, suction strengths, cycle speeds, and power source specifications. However, the differences in technological characteristics do not raise different questions of safety and effectiveness.

7. Summary of Non-Clinical Performance Testing

Testing for the AOV Wearable Breast Pump included use life testing, software, electrical safety, electromagnetic compatibility, biocompatibility and bench testing.

7.1 Biocompatibility

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA guidance 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 evaluated for the patient-contacting components:

- Cytotoxicity per ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

- Sensitization per ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- Irritation per ISO 10993-23:2021 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 noncytotoxic, 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:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021] 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 (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)]
- 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, and found to comply with all relevant sections.

7.3. Software Verification and Validation Testing

Software verification and validation testing consistent with a Basic documentation level per the FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" dated June 14, 2023. System validation testing presented in this 510(k) demonstrated that all software requirement specifications were met, and all software hazards have been mitigated to acceptable risk levels.

7.4. Performance Testing

1) Vacuum performance testing, cycle performance testing, and backflow protection testing was conducted. All the test results complied with the design specifications of the subject device throughout the use life.

2) Use life testing was conducted to demonstrate that the device maintains its performance specifications throughout its proposed use-life

3) Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life

4) Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.

8. Conclusions

The results of the performance testing described above demonstrate that the AOV Wearable Breast Pump (AOV6853, AOV6860, AOV6861, AOV6862)) is as safe and effective as the predicate devices and supports a determination of substantial equivalence.