May 9, 2024

Jiangxi AOV Maternity & Baby Products Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, Shanghai 200120
CHINA

Re: K232477
Trade/Device Name: Electric Breast Pump (Models AOV6818, AOV6821, AOV6826, AOV6830, AOV6852)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: July 2, 2023
Received: August 16, 2023

Dear Diana Hong:

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.

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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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)*
K232477

Device Name
Electric Breast Pump (Models AOV6818, AOV6821, AOV6826, AOV6830, AOV6852)

Indications for Use *(Describe)*
The Electric Breast Pump (Models AOV6818, AOV6821, AOV6826, AOV6830, and AOV6852) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Electric Breast Pump 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.

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510(k) Summary
K232477

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR 807.92.

1. Date of 510(k) Summary Preparation: May 7, 2024

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
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4. Device Information

Trade Name: Electric Breast Pump (Models AOV6818, AOV6821, AOV6826, AOV6830, AOV6852)
Common Name: Powered Breast Pump
Regulation Name: Powered Breast Pump
Regulation Number: 21 CFR 880.5160
Product Code: HGX (Pump, Breast, Powered)
Regulatory Class: II

5. Predicate Device Information

510(k) Number: K211024
Product Name: Electric Breast Pump (Models 918, HF918)

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

6. Device Description:

The subject devices, Electric Breast Pump (Models AOV6818, AOV6821, AOV6826, AOV6830, AOV6852), are powered breast pumps to be used by lactating women to express and collect milk from their breast. The proposed devices are battery powered, software-controlled, and intended for a single user. The devices are intended for home use.

The subject devices have the following modes: Massage mode, Expression mode, Bionic mode, Frequency Conversion mode A, Frequency Conversion mode B, Continuous suck mode and Mixed mode; each mode has multiple levels. Massage mode is for stimulating breast milk secretion. Expression mode is for pumping breast milk. Bionic mode cycles between massaging for 2 cycles and expressing for 2 cycles. Frequency Conversion mode A cycles between massaging for 3 cycles and expressing for 1 cycle. Frequency Conversion mode B cycles between massaging for 3 cycles and expressing for 2 cycles. Continuous suck mode applies a lower suction followed by a hold and then a second increase in suction before release as a cycle. Finally, Mixed mode cycles between massaging for 3 cycles and expressing for 1 cycle at levels 1-6, then cycles between massaging for 3 cycles and expressing for 2 cycles at levels 7-9.

Table 1 Working mode differences between 5 models of the proposed device

Model	Modes
AOV6818	Massage mode, Expression mode, Bionic mode, Frequency Conversion mode B
AOV6821	Massage mode, Expression mode, Continuous suck mode, Mixed mode
AOV6826	Massage mode, Expression mode
AOV6830	Massage mode, Expression mode, Frequency Conversion mode A
AOV6852	Massage mode, Expression mode, Bionic mode, Frequency Conversion mode A

The subject devices can be used in a single or double pumping configuration and have anti-backflow protection. The subject devices have a USB connecting cable and matching power adapter to supply power to the device. The subject devices are provided non-sterile and are not to be sterilized by the user prior to use. Each device includes a breast shield assembly, collection bottles, tubing set, feeding accessories, power adapter (for charging), and pump unit. The breast shield assembly includes a silicone breast shield and polypropylene breast shield body, which contacts the user’s breast.

7. Indications for Use:

The Electric Breast Pump (Models AOV6818, AOV6821, AOV6826, AOV6830, and AOV6852) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Electric Breast Pump is intended for a single user.

8. Comparison of Intended Use and Technological Characteristics

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

Table 1 General and Technological Comparison

ITEM	**Subject Device** **Electric Breast Pump (Models AOV6818, AOV6821, AOV6826, AOV6830, and AOV6852)** **K232477**	**Predicate Device** **Electric Breast Pump (918, HF918)** **K211024**	**Remark**
Product Code	HGX	HGX	Same
Class	II	II	Same
Regulation No.	21 CFR 884.5160	21 CFR 884.5160	Same
Indications for Use	The Electric Breast Pump (Models AOV6818, AOV6821, AOV6826, AOV6830, and AOV6852) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Electric Breast Pump is intended for a single user.	The Electric Breast Pump (Models 918, HF918) is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Electric Breast Pump is intended for a single user.	Same
Patient Population	Breastfeeding women	Breastfeeding women	Same
Anatomical Sites	Breast	Breast	Same
Single User	Yes	Yes	Same
Provided Non-sterile	Yes	Yes	Same
Direct user contact	Yes	Yes	Same
Re-usable	Yes	Yes	Same
Pumping Options	Single and Double Pumping	Single and Double Pumping	Same
Visual Indicator	LED	LED	Same
Backflow Protection	Yes	Yes	Same
Suction level	Massage mode: AOV6818: 9 levels AOV6821: 6 levels AOV6826: 5 levels AOV6830: 9 levels AOV6852: 9 levels	918&HF918: 5 levels	Different

	Expression mode: AOV6818: 9 levels AOV6821: 9 levels AOV6826: 9 levels AOV6830: 9 levels AOV6852: 9 levels	918&HF918:7 levels	
	Bionic mode: AOV6818: 9 levels AOV6852: 9 levels	918&HF918: 7 levels	
	Frequency Conversion mode B: AOV6818: 9 levels	918&HF918: 7 levels	
	Continuous suck mode: AOV6821: 6 levels	918&HF918: 1 level	
	Mixed mode: AOV6821: 9 levels	/	
	Frequency Conversion mode A: AOV6830: 9 levels AOV6852: 9 levels	/	
Mode and Suction strength (±5 mmHg)	Massage mode: AOV6818: 80-200 AOV6821: 100-200 AOV6826: 80-180 AOV6830: 80-200 AOV6852: 80-200	Stimulation mode: 918&HF918:60-217.5	Different
	Expression mode: AOV6818: 150-280 AOV6821: 160-280 AOV6826: 120-280 AOV6830: 120-280 AOV6852: 100-260	Expression mode: 918&HF918:105-285	
	Bionic mode: AOV6818: min:80/240 max: 200/280 AOV6852: min:80/100 max: 200/260	Two-in One mode: 918&HF918: Min: 75/90 Max:150/285	
	Frequency Conversion mode B： AOV6818: min:80/240 max:200/280	Dual-frequency mode: 918&HF918: Min: 67.5/105 Max: 187.5/277.5	
	Continuous suck mode: AOV6821: min:60/200	Simulation mode: 918&HF918:187.5	

	max: 110/280		
	Mixed mode: AOV6821: min: 100/220 max:180/280	/	
	Frequency Conversion mode A: AOV6830: min:80/220 max:200/280 AOV 6852: min:80/100 max:180/260	/	
Cycling Speed (±2 times/Min)	Massage mode: AOV6818: 39-95 AOV6821: 36-55 AOV6826: 42-91 AOV6830: 30-98 AOV6852: 59-128	918&HF918: 39-123	Different
	Expression mode: AOV6818: 25-61 AOV6821: 23-44 AOV6826: 24-60 AOV6830: 23-60 AOV6852: 40-89	918&HF918:24-84	
	Bionic mode: AOV6818: 30-50 AOV6852: 47-105	Two-in-One mode: 918&HF918: 59-123	
	Frequency Conversion mode B: AOV6818: 32-55	Dual-frequency mode: 918&HF918: 39-85	
	Continuous suck mode: AOV6821: 32-42	Simulation mode: 918&HF918: 14	
	Mixed mode: AOV6821: 30-46	/	
	Frequency Conversion mode A: AOV6830: 28-52 AOV6852: 60-116	/	
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Biocompatibility	Meets Attachment G recommendations (FDA Guidance document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a	No cytotoxicity, irritation or sensitization	Same

	risk management process" (issued September 2023))		

The subject and predicate device have same indications for use statements, and the same intended use. They are both used to express and collect milk from a lactating woman's breast.

The technological differences between the subject devices and the predicate devices are pumping options, suction levels, suction strength, and cycle speed. These differences do not raise different questions of safety and effectiveness.

9. Non-Clinical 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.

Electrical Safety and Electromagnetic Compatibility

- IEC 60601-1:2005, AMD1:2012, 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 Compatibility
- IEC 60601-1-11:2015, 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.
- 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

Biocompatibility

This device meets the recommendations of Attachment G of the 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" (issued September 2023). Therefore, this device is considered biocompatible.

Software Verification

- Software verification in accordance with the FDA Guidance document "Content of Premarket Submissions for Device Software Functions" dated June 14, 2023.

Performance Testing

Suction strength of subject devices was tested. All the test results complied with the design specifications of the subject device throughout the use life.

Backflow and overflow testing were conducted to ensure that even if the bottle is over-filled, no liquid will backflow into the tubing, and therefore no liquid can backflow into the pump motor. The test results showed that there was no backflow during the test.

Cycle speed of subject devices was tested. All the test results complied with the design specifications of the subject devices throughout the use life.

Battery 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 Electric Breast Pump (Models AOV6818, AOV6821, AOV6826, AOV6830, AOV6852) are as safe and effective as the predicate device and supports a determination of substantial equivalence.