October 12, 2022

Ameda, Inc.
Sean Pettibone
Coo
485 Half Day Road; Suite 320
Buffalo Grove, Illinois 60089

Re: K221576
Trade/Device Name: Ameda Pearl Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 30, 2022
Received: June 1, 2022

Dear Sean Pettibone:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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)*
K221576

Device Name
Ameda Pearl Electric Breast Pump

Indications for Use *(Describe)*
The Ameda Pearl Electric Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Ameda Pearl Electric Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by 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 – K221576

In accordance with 21 CFR 807.92(a) the following summary is provided:

SUBMITTER:

Ameda, Inc.
485 Half Day Road, Suite 320
Buffalo Grove, IL 60089
Phone: 847-964-2620

PRIMARY CONTACT PERSON:

Carolin Archibald
President and CEO
Ameda, Inc.
847-964-2620
carolin.archibald@ameda.com

DATE PREPARED: October 12, 2022

Device information

Trade Name: Ameda Pearl Electric Breast Pump
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: II

Predicate Device Information

Spectra S3 Plus: **K181784**

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

Device Description

The Ameda Pearl Electric Breast Pump is an electric breast pump powered by an external AC-DC power supply or its internal rechargeable lithium-ion battery. The device is provided non-sterile.

The device is intended to be used by lactating women to express and collect milk from their breasts. Pumping can be performed on either one breast (single pumping) or both breasts at the same time (double pumping).

The Ameda Pearl Electric Breast Pump utilizes a DC-powered motor driving a diaphragm-type vacuum pump and an electromechanical solenoid which are controlled electronically to provide a range of user-selectable vacuum (suction) levels and pumping (cycle) speeds. Vacuum is monitored continuously by a sensor mounted on an internal printed circuit board.

The Ameda Pearl Electric Breast Pump has a backlit LCD display, which shows pumping mode, suction level, cycle speed level, timer, and battery charge level. Surrounding the front panel display are eight soft-touch buttons allowing the user to power the device on/off, switch between stimulation and expression pumping modes, control vacuum strength and cycle speed, and adjust the lighting intensity of the LCD display and of a nightlight which shines from the underside of the pump handle.

There are 6 levels of suction strength in stimulation mode and 12 levels in expression mode. While the user can select any of 6 available cycle speeds at each of the 12 vacuum levels in expression mode, the cycle speed in stimulation mode is pre-set at each of the 6 vacuum levels available in that mode. At minimum vacuum, level 1, the cycle speed is highest, 120 CPM (cycles per minute). Medium vacuum levels 2 and 3 are cycled at 100 CPM, and the highest 3 vacuum levels are delivered at 80 CPM.

The Ameda Pearl Electric Breast Pump is primarily intended for multiple users in a hospital environment. Use is also expected in the home environment. When properly connected, the Ameda Hygienikit pumping kit transfers the vacuum generated by the powered pump to the breast enabling expression and collection of milk. A diaphragm in the breast flange assembly physically isolates pump and tubing from the air space where milk is expressed and collected, protecting the breast milk from contamination.

The Ameda Pearl Electric Breast Pump is supplied with an AC adapter. HygieniKit is not included.

Indications for Use

The Ameda Pearl Electric Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Ameda Pearl Electric Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.

Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Device

The intended use and key technological characteristics of the Ameda Pearl Electric Breast Pump and the predicate device are compared side-by-side in the table below.

	Subject Device	***Predicate Device***
Device name	Ameda Pearl Electric Breast Pump	Spectra S3 Plus Breast Pump
510(k) Number	K221576	K181784
Manufacturer	Ameda, Inc.	Uzinmedicare Co.
Product Code	HGX	HGX
Device Class	2	2
Indications for Use	The Ameda Pearl Electric Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Ameda Pearl Electric Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.	The Spectra 3 Plus Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The Spectra 3 Plus Breast Pump is intended for multiple users in a hospital setting. It is also intended for home use by a single user.
Intended Use Environment	Hospital and Home Healthcare	Hospital and Home Healthcare
POWER		
Power Source (external)	AC/DC adapter 15V, 2A DC	AC/DC adapter 12V, 2A DC
Power Source (internal)	Rechargeable lithium-ion battery, 10.8V, 2600 mAh	Rechargeable lithium-ion battery, 11.1V, 2000 mAh
Battery performance	4 hours on full charge	3 hours on full charge
Auto Power-off	After 60 minutes in expression mode	After 30 minutes in expression mode
VACUUM PERFORMANCE		
Pump Type	Diaphragm	Diaphragm
Modes	Stimulation and Expression	Massage and Expression
Vacuum levels	6 in stimulation mode 12 in expression mode	5 in massage mode 12 in expression mode
Vacuum range	30 – 250 mm Hg	50 – 270 mm Hg

	Subject Device	***Predicate Device***
Cycle speed range	80, 100, 120 cycles/minute (stimulation mode) 30 – 48 cycles/minute (expression mode)	70 cycles/minute (massage mode) 38 – 54 cycles/minute (expression mode)
USER INTERFACE		
LCD Display	Mode, Time, Vacuum Level, Battery Status, Cycle speed	Mode, Time, Vacuum Level, Battery Status, Cycle speed
LCD brightness	3-level adjustable	Non-adjustable
Night light brightness	3-level adjustable	2-level adjustable
Button controls	8: Power, Mode, Suction increase and decrease, Cycle Speed increase and decrease, LCD brightness, Night light brightness	7: Power, Mode, Suction increase and decrease, Cycle Speed increase and decrease, Night light brightness

The subject and predicate device have identical indications for use statement and have the same intended use. The subject and predicate device have different technological features, including the user interface, vacuum range, cycle speed range, and power sources. These technological differences do not raise different questions of safety or effectiveness.

Summary Of Non-Clinical Testing

The following data were provided in support of the substantial equivalence determination.

Risk Analysis in accordance with ISO 14971:2019

Electrical safety testing per IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012

Electromagnetic compatibility testing per IEC 60601-1-2: 2014+AMD1:2020, edition 4.1

Use in the home healthcare environment per IEC 60601-1-11:2015

Software verification and validation was conducted in accordance with the 2005 FDA guidance document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices." The software for this device was considered a Moderate level of concern.

Bench Performance Testing

The Ameda Pearl Electric Breast Pump was tested to demonstrate it meets stated performance specifications (vacuum pressure and cycle speed). Testing involved measurement of vacuum at user-selectable settings in both stimulation and expression modes for pumping at a single breast (single pumping) or both breasts simultaneously (double pumping). Testing was conducted separately under two states of power: (1) externally supplied by an AC/DC adapter and (2) internally supplied from a rechargeable lithium-ion battery. Specifications were met under all conditions.

Testing confirmed device life and battery operating time, battery indicator accuracy, and protection against backflow and overflow.

Conclusion

The results of the performance testing described above demonstrate that the Ameda Pearl Electric Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.