April 22, 2021

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

Re: K203570
Trade/Device Name: Mya Joy PLUS Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: March 22, 2021
Received: March 23, 2021

Dear Sean GM 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,

For
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

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)*
K203570

Device Name
Mya Joy PLUS Breast Pump

Indications for Use *(Describe)*
The Ameda Mya Joy PLUS breast pump is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.

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

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

PREPARED: April 16, 2021

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

Device information

Trade Name: Mya Joy PLUS Breast Pump
Common name: Powered Breast Pump
Classification Name: PUMP, BREAST, POWERED
Classification Panel: Obstetrics/Gynecology
Classification Regulation: 21 CFR 884.5160
Regulatory Class: II
Product Code: HGX

Predicate Device Information

Cimilre F1: **K162870**

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

Device Description

The Mya Joy PLUS Breast Pump is an electric breast pump powered by an external AC-DC power supply or by an 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 Mya Joy PLUS 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 at various pre-determined cycle frequencies.

The Mya Joy PLUS Breast Pump has a backlit LCD display, which shows pumping mode, suction level, timer, and battery level. The device also has four soft-touch buttons allowing the user to power the device on/off, switch between stimulation and expression pumping modes and control vacuum strength within each mode, 6 levels of vacuum strength in stimulation and 12 levels in expression.

The Mya Joy PLUS Breast Pump is intended for a single user 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 space where milk is expressed, flows and is collected, effectively protecting the breast milk from contamination.

The pump allows lactating women to express milk at their own convenience and maintain their milk supply.

The base model of the Mya Joy PLUS Breast Pump contains a pump, pumping kit, AC adapter with detachable USB-C cable, and a lanyard. Optional accessories, such as a carrying bag or spare parts for the pumping kit, may be included in the packaging of other product offerings.

Indications for Use

The Ameda Mya Joy PLUS breast pump is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.

Comparison of Technological Characteristics

The indications for use of the Ameda Mya Joy PLUS breast pump and the intended use are the same as those of the predicate device, the Cimilre F1 powered breast pump (K162870). It has a nearly identical external shape, user interface, similar vacuum motor, including noise dampening material.

Key technological characteristics of the Ameda Mya Joy PLUS breast pump and the predicate device are compared side-by-side in the table below.

	Proposed Device	***Predicate Device***
Device name	Mya Joy PLUS	F1
510(k) Number	TBD	K162870
Manufacturer	Ameda, Inc.	Cimilre
Product Code	HGX	HGX
Device Class	2	2
Indications for Use	The Ameda Mya Joy PLUS breast pump is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.	The CIMILRE F1 is a single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women
Intended Use Environment	Home Environment	Home Environment
POWER		
Power Source (external)	AC/DC adapter; 5VDC	AC/DC adapter: 12 VDC
Power Source (internal)	rechargeable lithium-ion battery 3.7V, 1500 mAh	rechargeable lithium polymer battery 7.4V, 900 mAh
Battery performance	at least 2 hours on full charge	2 hours on full charge
Auto Power-off	After 45 minutes in expression mode	After 30 minutes in expression mode
VACUUM PERFORMANCE		
Pump Type	Diaphragm	Diaphragm
Pump Options	Single or Double	Single or Double
Modes	Stimulation and Expression	Massage and Expression
Vacuum levels	6 (stimulation) 12 (expression)	5 (massage) 10 (expression)
Vacuum range	40 – 250 mm Hg	40 – 280 mm Hg

	Proposed Device	***Predicate Device***
Cycle range	80 – 120 cycles/minute (stimulation) 25 – 63 cycles/minute (expression)	25 – 60 cycles/minute (CPM)
Cycle speed	Pre-programmed	Pre-programmed
Noise level	43dB	< 45 dB
USER INTERFACE		
LCD Display	Mode, Time, Vacuum Level, Battery	Mode, Time, Vacuum Level, Battery
Button controls	Power, Mode, Increase, Decrease	Power, Mode, Increase, Decrease
Pumping Kit		
Backflow Protection	cylindrical diaphragm	circular diaphragm
Integrated flange	Yes	Yes
Flange and Bottle Material	Polypropylene	Polypropylene
Valve Design	Duckbill	Duckbill
Valve Material	Silicone	Silicone

The principal differences in technological characteristics between the subject device and the predicate are few. Both devices utilize lithium-based technology for the internal rechargeable battery. The subject device has a higher battery capacity than the predicate (1500mAh). The longer time before automated shut-off in the subject device is not consequential because users will likely finish a pumping session before auto-cutoff is reached in either device. These power-related differences do not alter the intended use of the device from that of the predicate. Moreover, these differences do not raise different questions of safety and effectiveness.

Vacuum performance characteristics differ slightly. The subject device includes additional range in stimulation mode and two ranges in expression mode relative to the ranges available in the predicate device. The subject device delivers lower maximum pressure (250 mmHg) than the predicate. Finally, while the cycle speed of the subject device is very similar to that of

the predicate device in expression mode, the cycle speed of the subject device is nearly twice as high as that of the predicate in the stimulation mode. These differences in vacuum pressure, speed and settings do not alter the indications for use or intended use of the device, and they do not raise new questions of safety and effectiveness.

Both kits feature an integrated breast flange design, namely flanges that are molded together with the connections to the pump and bottle threads. The only difference between subject and predicate devices is the shape of the diaphragm. In the subject device, the cylindrical shape of the diaphragm results in tubing which rises vertically from the flange assembly, while the flat circular shape of the diaphragm in the predicate device allows tubing to lie horizontally. This difference in design does not affect pump performance, does not alter intended use, and raises no new questions of safety and effectiveness.

Summary of Non-Clinical Tests

The Ameda Mya Joy PLUS breast pump complies with recognized voluntary standards for risk management, electrical safety, electromagnetic compatibility, use in the home healthcare environment, biocompatibility and lithium-ion battery safety.

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

Risk Analysis in accordance with ISO 14971:2007

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 (Edition 4.0)

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

Biocompatibility testing per ISO 10993-5:2009 and ISO 10993-10:2010

Lithium-ion battery safety testing per IEC 62133-2:2017 (Edition 1.0)

Performance Testing

The Ameda Mya Joy PLUS breast pump was tested to demonstrate it meets stated performance specifications. 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 was also performed to characterize noise emitted from the pump during operation, the ability of the pump to operate within stated operating and storage conditions, and the ability of packaging to withstand simulated transportation conditions.

Testing also confirmed device life and battery operating time.

Test results demonstrated that the Ameda Mya Joy PLUS breast pump met predetermined acceptance criteria.

Summary of Clinical Tests

Clinical testing was not required to demonstrate the substantial equivalence of the Ameda Mya Joy PLUS breast pump to its predicate device.

Conclusion

The Ameda Mya Joy PLUS breast pump has the same intended use and very similar technological characteristics as the predicate device. The minor differences in technological characteristics do not raise different questions of safety and effectiveness. In addition, performance testing demonstrates that the subject device is as safe and effective as the predicate.

Therefore, Ameda concludes that the Ameda Mya Joy PLUS breast pump is substantially equivalent to the legally marketed predicate device, the Cimilre F1 powered breast pump.