April 15, 2022

ARDO Medical AG
% Kristin Zielinski Duggan
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, DC 20004

Re: K212773
Trade/Device Name: Ardo Alyssa
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: March 14, 2022
Received: March 14, 2022

Dear Kristin Zielinski Duggan:

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

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)*
K212773

Device Name
Ardo Alyssa

Indications for Use *(Describe)*
The Ardo Alyssa is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Ardo Alyssa 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

K212773

Submitter Information:

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Date 510(k) Summary Prepared: April 14, 2022

Device Information:

Name of Device:	Ardo Alyssa
Common or Usual Name:	Powered breast pump
Regulation Name:	Powered breast pump
Regulation Number:	21 CFR 884.5160
Regulatory Class:	Class II
Product Code:	HGX (Pump, Breast, Powered)
Review Panel:	Obstetrics/Gynecology

Predicate Device:

510(k) Number:	K191653
Manufacturer:	Medela AG
Device Name:	Fleestyle Flex™

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

Device Description:

The Ardo Alyssa is a powered breast pump that generates negative pressure to express milk from the breasts of lactating women. It is intended for a single user and can be used in professional healthcare and home environments. The pump can be used for single or double breast pumping. To operate as a single or double pumping system, the pump needs to be connected to a single or

double pump set. Pump sets to be provided with the Ardo Alyssa are identical to those cleared in K141742 for the Ardo Calypso Powered Breast Pump.

The Ardo Alyssa has two operational modes (stimulation and expression), with eight vacuum levels in each mode. The device comprises an ON/OFF button and two +/- buttons for independently adjusting (increasing or decreasing) vacuum and cycle. The user also has an option to operate the device via the mobile app, MyArdoApp. A memory function enables storing and replaying a pump session, and a power pumping button enables execution of a predefined pump-pause program. The pump can be powered using the supplied power adapter or by an integrated rechargeable battery.

Indications for Use:

The Ardo Alyssa is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Ardo Alyssa is intended for a single user.

Comparison of Intended Use and Technological Characteristics:

The following table compares the subject device to the predicate device with respect to the indications for use and technological characteristics:

Device & Predicate Device:	Subject Device Ardo Alyssa K212773	Predicate Device Freestyle Flex™ K191653
Indications for Use	The Ardo Alyssa is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Ardo Alyssa is intended for a single user.	The Freestyle Flex™ breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Freestyle Flex™ breast pump is intended for a single user. The breast pump is intended to be used in a home environment.
Intended Use	Single-user	Single-user
Modes of operation	Stimulation mode, Expression mode	Stimulation mode, Expression mode
Pumping options	Single and double	Single and double
Vacuum strength and levels	Stimulation mode: 23 – 113 mmHg, 8 levels Expression mode: 23 – 248 mmHg, 8 levels	Stimulation mode: 45 – 140 mmHg, 9 levels Expression mode: 45 – 245 mmHg, 9 levels
Cycle speed	Stimulation mode: 72 – 120 cycles/min Expression mode: 20 – 50 cycles/min	Stimulation mode: 111 cycles/min Expression mode: 45 – 75 cycles/min
Power source	AC adaptor: 100 – 240 V, 50/60 Hz, 400 mA (Output: 5VDC, 2A) Li-ion battery (3.7 V, 2600mAh)	AC adaptor: 100 – 240 V, 50/60 Hz, 400 mA (Output: 5VDC, 2A) Li-ion battery (3.7 V, 2750mAh)
Backflow protection	Diaphragm	Diaphragm
Device control through an app	Yes	Yes

The subject and predicate device do not have identical indications for use statements but do have the same intended use – to express and collect milk from the breasts of lactating women. The subject and predicate device have different technological characteristics, including vacuum pressures, cycle speeds, and battery specifications. These differences do not raise different questions of safety or effectiveness.

Performance Testing:

Non-clinical tests were conducted to verify that the Ardo Alyssa met all design specifications and that it is substantially equivalent to the predicate device. The testing performed is summarized below:

a. Biocompatibility testing on the patient-contacting materials of the device was not provided in this submission, as all of the patient-contacting materials are identical to those cleared in K141742 for the Ardo Calypso Powered Breast Pump. Therefore, this submission relied on the biocompatibility information from the Ardo Calypso Powered Breast Pump to support the patient-contacting materials of the subject device.

b. Electrical Safety, Electromagnetic Compatibility, and Wireless Technology
   - IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance with US deviations per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012.
   - 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 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility
   - 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
   - UL 1642 – Standard for Safety: Lithium batteries
   - Documentation provided in accordance with the FDA guidance document, “Radio Frequency Wireless Technology in Medical Devices” dated August 14, 2013.

c. Software verification and validation in accordance with the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” dated May 11, 2005.

d. Cybersecurity information was provided in accordance with the FDA guidance document, “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” dated October 2, 2014.

e. Performance testing was conducted to confirm that the subject device meets all performance specifications and operates as intended. The following were evaluated with passing results:

   - Vacuum pressure and cycle rate testing was conducted at all settings and demonstrated that the device met its specifications.
   - Backflow testing was conducted to demonstrate that liquid does not backflow into the tubing/pump.
   - 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 displays the correct remaining battery operation time.

Conclusion:

The subject and predicate device have the same intended use and the technological differences do not raise different questions of safety or effectiveness. The performance data demonstrate that the Ardo Alyssa is as safe and effective as the Medela Freestyle Flex™ and supports a determination of substantial equivalence.