March 30, 2023

ARDO Medical AG
% Thomas Reichthalhammer
Partner
Medtech360
Am Wasser 14
Polling, Bavaria 84570
Germany

Re: K230590
Trade/Device Name: Ardo Bellis
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: February 27, 2023
Received: March 3, 2023

Dear Thomas Reichthalhammer:

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 -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230590

Device Name
Ardo Bellis

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

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 – K230590

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Date Prepared: March 29, 2023

Device Information:

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

Predicate Device:
ARDO Medical AG, Alyssa, K212773

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

Device Description

The Ardo Bellis is a breast pump unit for collecting breast milk by application of a defined vacuum with a defined frequency on a woman's breast. The pump needs to be connected to a single or double pump set (Carum and Calypso Powered Breast Pumps, cleared under K141742) to be used on one or two breasts. The case and controls of the pump unit have limited contact with the user and are intended only to control the activities of the device parts that contact the user's breast.
The device is comprised of an ON/OFF button and two +/- buttons for adjusting (increasing or decreasing) the vacuum and cycle speed. The pump can also be operated using the accompanying mobile application. A memory function enables storing and replaying a pump session, and a power pumping button enables execution of a predefined pump-pause program. An integrated battery allows for portable use of the device. With the supplied power adapter, the device can be re-charged.

Ardo Bellis can be used indoors in professional as well as home care environments.

Indications for Use

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

Comparison of Intended Use and Technological Characteristics with the Predicate Device

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

Table 1. Comparison of indications for use and technological characteristics

	Subject Device Ardo Bellis K230590	**Predicate Device Ardo Alyssa K212773**
Indications for Use	The Ardo Bellis is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Ardo Bellis is intended for a single user and multiple users.	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.
Intended Use	Multiple users	Single-user
Modes of operation	Same as predicate	Stimulation and expression mode
Pumping options	Same as predicate	Single and double
Vacuum strength and levels	Same as predicate	Stimulation mode: 23-113 mmHg, 8 levels Expression mode: 23-248 mmHg, 8 levels
Cycle speed	Same as predicate	Stimulation mode: 72-120 cycles/min Expression mode: 20-50 cycles/min
Power source	Same as predicate	AC adapter: 100-240 V, 50/60 Hz, 400 mA (Output: 5VDC, 2A) Li-ion battery (3.7 V, 2600 mAh)
Device control through an app	Same as predicate	Yes

The purpose of this Special 510(k) submission is to modify the indications for use statement for the subject device to include multiple users. As shown in the table above, the subject and predicate devices have different indications for use statements; however, intended uses of the predicate and subject devices are the same (i.e., to express and collect milk from the breasts of lactating women).

The only technological difference between the subject and predicate devices is the case design (difference in shape, size, and weight), as shown in the table below. This difference does not raise different questions of safety or effectiveness.

Table 2. Case differences between subject and predicate devices

Case of Ardo Bellis subject of this 510k application	**Case of Ardo Alyssa predicate device K212773**
	

Performance Data

The changes made to the design and indications for use of the subject device do not raise different questions of safety and effectiveness. Therefore, the performance testing included in K212773 can be leveraged to support the safety and effectiveness of the subject device.

Conclusions

The information described above demonstrate that the Ardo Bellis is as safe and effective as the predicate device and supports a determination of substantial equivalence.