DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

June 19, 2015

Ardo Medical Ag
% Yarmela Pavlovic
Partner
Hogan Lovells US LLP
3 Embarcadero Center, Suite 1500
San Francisco, CA 94111

Re: K150721
Trade/Device Name: Ardo Calypso Pro Powered Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: March 19, 2015
Received: March 19, 2015

Dear Yarmela Pavlovic,

This letter corrects our substantially equivalent letter of June 17, 2015.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150721

Device Name
ARDO Calypso Pro Powered Breast Pump

Indications for Use *(Describe)*
The ARDO Calypso Pro breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for 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
ARDO'S CALYPSO PRO POWERED BREAST PUMP

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Roger Dubach

Date Prepared: March 19, 2015

Name of Device

CALYPSO PRO, POWERED BREAST PUMP

Name/Address of Correspondent

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Common or Usual Name

Powered breast pump

Classification Name

HGX, Powered breast pump
21 C.F.R. § 884.5160

Predicate Device

Calypso Powered Breast Pump (K141742)

Device Description

The ARDO Calypso Pro Powered Breast Pump is a single piston pump for hospital, rental and personal use. The unit is equipped with a robust plastic housing and a simplified, logically-organized keyboard with an LCD display readout.

The electrical equipment is designed for outlet and for car battery-operation, or for (optional) battery use. The controls allow each mother to customize the settings through a flexible system for

adjusting vacuum and cycles. The ARDO Calypso Pro breast pump's vacuum level remains stable when the user changes the cycle setting. Likewise, the cycle level remains stable when the user changes the vacuum setting.

Accessories for Calypso Pro include:

- Pumpset (single or double)
- Power cord;
- Bottle holder;
- Nylon bags for accessories and for the PumpSet;
- EasyFreeze bag;
- Breastfeeding bag (Shoulder Bag consisting of cold bag, cooling elements, Calypso bag and Pumpset bag); and
- Pumpsets.

Intended Use / Indications for Use

The ARDO Calypso Pro breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for multiple users.

Technological Characteristics

The ARDO Calypso Pro breast pump is a single piston pump for hospital, rental and personal use. The unit is equipped with a robust plastic housing and a simplified, logically organized keyboard with an LCD display readout. The electrical equipment is designed for outlet or car battery-operation, or for (optional) battery use. The controls allow each mother to choose customized vacuum and cycle settings. The ARDO Calypso Pro breast pump includes a battery compartment and outlet adapter. The device is identical to the predicate device previously cleared by FDA.

The accessories for the ARDO Calypso Pro breast pump are the same as the accessories for the previously cleared ARDO Calypso breast pump. The accessories were previously cleared under K141742, along with the predicate Calypso breast pump. Accessories for Calypso Pro breast pump include:

- Power cord;
- Bottle holder;
- Nylon bags for accessories and for the PumpSet;
- EasyFreeze bag;
- Breastfeeding bag (Shoulder Bag consisting of cold bag, cooling elements, Calypso bag and Pumpset bag); and
- Pumpsets.

Performance Data

The ARDO Calypso Pro breast pump is identical to the previously cleared ARDO Calypso breast pump, except for a minor difference in the indications for use. There have been no device changes since the last 510(k) notification. Thus, further performance testing was not necessary.

Substantial Equivalence

The ARDO Calypso Pro breast pump is substantially equivalent to the ARDO Calypso breast pump. The ARDO Calypso Pro breast pump is identical to the predicate device except for a minor difference in the indications for use. The minor difference in the indications for use between the ARDO Calypso Pro breast pump and the ARDO Calypso breast pump does not raise new issues of safety or effectiveness. There have been no device changes since the last 510(k) notification. Thus, the ARDO Calypso Pro breast pump is substantially equivalent to the predicate.

Conclusions

Based upon the information above, the ARDO Calypso Pro breast pump is substantially equivalent to the predicate device.

ARDO MEDICAL AG'S
CALYPSO PRO POWERED BREAST PUMP
SUBSTANTIAL EQUIVALENCE CHART

Feature	**New Device** Ardo medical AG Powered Breast Pump	**Predicate Device** Ardo medical AG, Powered Breast Pumps
	Calypso Pro Breast Pump	**Calypso Breast Pump**
Indication for use	The ARDO Calypso Pro breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for multiple users.	The ARDO Calypso breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for single users.
Suction Connection	1 suction connection, suitable for double pumping mode via Y connector	same
Power Supply	Adaptor: 100 V – 240 V 50/60 Hz	same
Electrical Safety	IEC 60601-1	same
EMC Emitted Interference	Complies with IEC 60601-1-2	same
EMC Interference Resistance	Complies with IEC 60601-1-2	same
Battery	Battery 6 x 1,5 V; 9 V, 1200 mA	same
Noise Level	< 55 dBA	same
Weight	Pump weight 0.545 kg	same
Vacuum range in stimulation mode	no stimulation mode available	same
Vacuum range in suction (expression) mode	50 – 330 mbar 37 – 250 mmHg	same
Cycle range in stimulation mode (cycles per minute)	no Stimulation mode available	same
Cycle range in suction (expression) mode (cycles per minute)	30 – 60 / min	same
Programs / Features	Suction Mode Vacuum and Cycle Frequency can be set independently	same
Alarms	Error Code in Display	same
Accessories	Pumpset with non-sterile Plastic Bottles	same
Patient Contacting Materials	Bormed HD810MO & ELASTOSIL LR 3003/50 A/B	same
Life-Cycle	Warranty: 400 operating hours	same