November 29, 2017

Ardo Medical AG
% Yarmela Pavlovic
Regulatory Counsel
Hogan Lovells US LLP
3 Embarcadero Center, Suite 1500
San Francisco, CA 94111

Re: K172067
Trade/Device Name: One Mum Pumpset
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: November 20, 2017
Received: November 20, 2017

Dear Yarmela Pavlovic:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172067

Device Name
One Mum Pumpset

Indications for Use *(Describe)*
The One Mum Pumpset should be used in combination with Ardo breastpumps and is intended to be used by lactating women to express and collect milk from their breast. The One Mum Pumpset can be used both as a single pumpset and as a double pumpset and is intended for single users only.

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 medical AG's One Mum Pumpset

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

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Date Prepared: November 29, 2017

Name of Device

One Mum Pumpset

Common or Usual Name

Pumpset

Classification

21 CFR 884.5160 (powered breast pump), Class II, product code HGX (pump, breast, powered)

Predicate Devices

Ardo Carum and Calypso Powered Breast Pumps (K141742). This predicate device has not been subject to a design-related recall.

Intended Use / Indications for Use

The One Mum Pumpset should be used in combination with Ardo breastpumps and is intended to be used by lactating women to express and collect milk from their breast. The One Mum Pumpset can be used both as a single pumpset and as a double pumpset and is intended for single users only.

Device Description

The One Mum Pumpset is a sterile pumpset accessory used by a single user in conjunction with the Ardo breastpumps. The Pumpset has nearly identical technological characteristics and identical principles of operation as the non-sterile pumpset previously cleared in the Ardo Carum and Calypso Powered Breast Pumps (K141742), with the minor difference being that the Pumpset is sterilized using an ethylene oxide gas cycle.

Like the predicate device non-sterile pumpset, the One Mum Pumpset consists of multiple components including a bottle, bottle cap, polypropylene breast shell, and silicon tubing kit that connects to the breast pump for the removal, collection, and storage of the mother's breast milk.

The Pumpset can be used both as a single pumpset and as a double pumpset and may be used in indoor settings including hospital and home.

Comparison of Technological Characteristics

The One Mum Pumpset is a sterilized version of the non-sterile pumpset previously cleared in the Ardo Carum and Calypso Powered Breast Pumps (K141742). The reason for this Special 510(k) is to describe the sterilization process and demonstrate adequate sterility validation of the proposed One Mum Pumpset. These changes do not raise different questions of safety and effectiveness.

Performance Data

Biocompatibility: The biocompatibility of the One Mum Pumpset has been established per ISO 10993 guidelines:

- Cytotoxicity Study Using the Elution Method per ISO 10993-5:2009
- Maximization Sensitization Study per ISO 10993-10:2010
- Intracutaneous Reactivity Study per ISO 10993-10:2010
- Systemic Toxicity Study per ISO 10993-11:2006

Test results demonstrate the One Mum Pumpset is not cytotoxic, non-sensitizing, non-irritating and not systemically toxic.

Sterilization Validation: Sterilization validation was completed to assure a sterility assurance level of level (SAL) of 10^{-6} per ISO 11135-1:2007. Residual testing was also conducted per ISO 10993-7:2008. Results demonstrate the sterilization process is valid and that the residual values are within appropriate limits.

Packaging and Shelf Life Validation: Accelerated and real-time aging studies have been conducted per ISO 11607-1:2009 on finished, sterilized devices and all performance specifications post-aging have been met. Packaging validation was completed to ensure packaging integrity.

In all instances, the One Mum Pumpset functioned as intended and met all the same acceptance criteria as the predicate.

Conclusion

The One Mum Pumpset is as safe and effective as the non-sterile pumpset (K141742). The One Mum Pumpset has the same intended use and the same principles of operation as its predicate device. The change in technological characteristics of sterilizing the device does not raise different questions of safety or effectiveness. Performance data demonstrate that the One Mum Pumpset is as safe and effective as the non-sterile pumpset. Therefore, the

One Mum Pumpset is substantially equivalent to the predicate.