August 6, 2018

UNIMOM CO.
Sang-Hyun Hong
President
110-19 Gajangsaneopseobuk-ro
Osan-si, Gyeonggi-do 18102
Korea

Re: K180075
Trade/Device Name: MINUET LCD, MINUET LCD eco
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: June 27, 2018
Received: July 5, 2018

Dear Sang-Hyun Hong:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Michael T. Bailey -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)*
K180075

Device Name
MINUET LCD, MINUET LCD eco

Indications for Use *(Describe)*
The MINUET LCD and MINUET LCD eco are multiple-user, powered breast pumps 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
(K180075)

1. Submitter Information

Submitter:	UNIMOM CO.
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2. Date Prepared: August 3, 2018

3. Device Information

Trade/Device Name	MINUET LCD, MINUET LCD eco
Common Name	Powered breast pump
Regulation Number	21 CFR 884.5160
Regulation Name	Powered Breast Pump
Product Code	HGX (Pump, Breast, Powered)
Regulatory Class	II

4. Predicate Device

Spectra S1 Plus and Spectra S2 Plus (K150476) manufactured by Uzinmedicare Co. The predicate device has not been subject to any design related recalls.

5. Device Description

The MINUET LCD and MINUET LCD eco are portable, multiple-user, powered breast pumps to be used in home or health care settings. These devices are the same, except the MINUET LCD has a rechargeable battery whereas the MINUET LCD eco does not. The devices have two major components: control unit (pump) and breast shield kit (breast shield, diaphragm, tubing, silicone massager, and bottle components). Users have the option of single or double pumping. The devices have two operating modes: massage and expression. The massage mode has seven suction levels whereas the expression mode offers nine suction levels. The vacuum strength range is 50-280 mmHg.

6. Indications for Use

The MINUET LCD and MINUET LCD eco are multiple-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.

7. Comparison of Intended Use and Technological Characteristics of the Subject Device and Predicate Device

Devices	K180075 (subject devices)	K150476 (predicate device)
Indications for Use	The MINUET LCD and MINUET LCD eco are multiple-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.	The Spectra S1 Plus and Spectra S2 Plus are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.
Pump type	Same as the predicate	Diaphragm
Vacuum strength	Same as the predicate	50-280 mmHg
Suction level	Massage Mode: 7 levels Expression Mode: 9 Levels	Massage Mode: 5 levels Expression Mode: 12 Levels
Cycle speed	Massage Mode: 23-120 cycles/min Expression Mode: 13-60 cycles/min	38-70 cycles/min
Back flow protection	Same as the predicate	Backflow protector (diaphragm) on the top of milk collection assembly
Visual indicator	Same as the predicate	LCD
Software control	Same as the predicate	Yes
Power supply - Mains	AC/DC adapter with micro USB cable	AC/DC converter
Power supply - Battery	Same as the predicate	Rechargeable lithium ion battery
Pump option	Same as the predicate	Single or double

The subject and predicate devices have the same intended use – expressing milk from the breasts of lactating women. They also use the same fundamental technology – a microprocessor-controlled diaphragm pump and a solenoid. They have the same vacuum strength range, backflow prevention mechanism, and pump options. They also have comparable power supplies.

The subject and predicate devices have different technological characteristics, as they have different suction levels under each operational mode. Also, the subject devices have high cycle speed up to 120 cycles/min under massage mode. These differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

8. Summary of Non-Clinical Performance Testing

The following studies have been conducted on the subject devices to support substantial equivalence to the predicate device:

- Biocompatibility studies on the breast shield, as follows:
  - Cytotoxicity testing per 10993-5:2009
  - Guinea Pig Maximization Sensitization testing per ISO 10993-10:2010
  - Irritation testing per ISO 10993-10:2010

- Electrical safety testing in accordance with:
  - IEC 60601-1:2005+ CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012)
  - IEC 60601-1-11:2015

- Electromagnetic compatibility testing per IEC 60601-1-2:2014
- Battery safety testing in accordance with:
  - AAMI/ANSI ES60601-1:2005
  - IEC 62133:2012
- Software verification and validation testing in accordance with FDA guidance: “The content of premarket submissions for software contained in medical devices” dated May 11, 2005
- Bench tests using internal test protocols to demonstrate device performance, including vacuum level settings, speed settings, backflow/cross-contamination protection, battery operation, and use-life

9. Conclusion

The subject and predicate devices have the same intended use. Although there are differences in technological characteristics between the subject and predicate devices, these differences do not raise different questions of safety or effectiveness. The performance data demonstrate that the subject devices are substantially equivalent to the predicate device.