August 30, 2019

Unimom Co.
Sang-Hyun Hong
President
110-19, Gajangsaneopseobuk-ro
Osan-si, 18102 Gyeongg1-do
KOREA

Re: K190810
Trade/Device Name: OPERA, OPERA eco
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: July 22, 2019
Received: July 29, 2019

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/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,

Sharon M. Andrews
Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190810

Device Name
OPERA & OPERA eco

Indications for Use *(Describe)*
The OPERA and OPERA 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 – K190810
[As Required by 21 CFR 807.92]

Submitter's Information

Submitter's Name:	Unimom Co.
Address:	110-19, Gajangsaneopseobuk-ro, Osan-si, Gyeonggi-do, 18102, KOREA [Zip.18102]
Contact Person:	Hong, Sang-Hyun
Telephone No.:	+82-70-8798-5577
Fax No.:	+82-31-372-6782
Email Address:	infounimom@naver.com

Date Prepared
August 29, 2019

Trade Name, Regulation Name, Classification

Trade/Device Name	OPERA & OPERA eco
Common Name	Powered breast pump
Classification Number	21 CFR 884. 5160
Classification Name	Powered breast pump
Regulation Class	Class II
Product Code	HGX
Product Code Name	Pump, Breast, Powered

Identification of Predicate Device

The identified predicate devices within this submission are shown as follow;

510(k) Number:	K180075
Applicant:	Unimom Co.
Trade/Device Name:	MINUET LCD, MINUET LCD eco
Classification Number:	21 CFR 884. 5160
Classification Name:	Powered breast pump
Regulation Class:	Class II
Product Code:	HGX

Product Code Name: Pump, Breast, Powered

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

Description of the Device

The OPERA & OPERA eco are multiple-user, powered breast pumps intended to express and collect milk from the breasts of lactating women. The OPERA & OPERA eco are provided non-sterile.
Two models are available; Opera and Opera eco.

- "OPERA" (pink color): powered by the adapter (AD/DC adapter, INPUT: AC 100 ~240V, 50/60Hz, OUTPUT: DC14V, 2A) or by the internal battery (Rechargeable Lithium polymer battery, 11.1 V, 2200 mAh).
- "OPERA eco" (blue color): powered by the adapter (AD/DC adapter, INPUT: AC 100 ~240V, 50/60Hz, OUTPUT: DC14V, 2A).

The OPERA & OPERA eco consists of a group of hardware and software components.
The hardware component(s) consist of:

- Opera or Opera eco pump body
- Breast Shield Set (Breast shield, K-POP Diaphragm, Bottle Stand, Bottle Disk, Bottle Cover, Bottle Cap, Bottle, Nipple, White Valve, Diaphragm Cap, Air Tube, Air Tube Connector, Silicone Massager)
- Adaptor

The OPERA & OPERA eco provide the following user features:

1) Two Modes
   - Massage Mode: 5 Levels
   - Expression Mode: 8 Levels
2) Adjustment of vacuum level/cycles
3) LCD Display, for user assistance/device status

Principle and Theory of Operation:
The Opera and Opera eco generate negative pressure on the breast and it moves diaphragm up and down to express and collect milk from the breasts of lactating women. To prevent backflow of breastmilk, Opera & Opera eco include a backflow protector on the top of breast shield. The inserted diaphragm blocks the upper side and bottom side of breast shield, which are the pathway of air and the breastmilk.

Indications for Use

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

Substantial Equivalence Comparison

The following table compares the indications for use statements and technological characteristics of the subject and predicate devices.

	Proposed Device	**Predicate Device**
Product Name	OPERA, OPERA eco	MINUET LCD, MINUET LCD eco
510(k) Number	Not known	K180075
Manufacturer	Unimom Co.	Unimom Co.
Product Code	HGX	HGX
Device Class	II	II
Indications for Use	The OPERA & OPERA eco are multiple- user, powered breast pumps intended to express and collect milk from the breasts of lactating women.	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.
Intended use environment	Hospital, Home environment	Hospital, Home environment
Specifications		
Power source (Adapter)	AC/DC Adapter - Rated input: AC 100~240V, 50/60Hz - Rated output: DC14V, 2A	AC/DC Adapter with Micro USB Cable - Rated input: AC 100~240V, 50/60Hz - Rated output: 5Vdc, 2A
Power source (Battery)	Rechargeable Lithium Polymer Battery (Only for OPERA)	Rechargeable Lithium Polymer Battery (Only for MINUET LCD)
Pump type	Diaphragm	Diaphragm
Pump Options	Single or Double	Single or Double
Mode	2 Modes (Massage Mode, Expression Mode)	2 Modes (Massage Mode, Expression Mode)
Vacuum Levels	Massage Mode: 5 Levels Expression Mode: 8 Levels	Massage Mode: 7 Levels Expression Mode: 9 Levels
Vacuum Strength	45 - 280 mmHg	50 - 280 mmHg
Cycle Range	Massage Mode : 60 – 100 cycles/min Expression Mode : 26 – 42 cycles / min	Massage Mode : 23 – 120 cycles/min Expression Mode : 13 – 60 cycles / min
User Interface	Switch control - Power, Vacuum / Cycle Up or Down - Mode switch LCD Display	Switch control - Power, Vacuum / Cycle Up or Down - Mode switch LCD Display
Accessories	Air Tube Breast Shield Kit with back-flow protector Bottle Bottle Cover Nipple Bottle Cap Bottle Disk Bottle Stand Adapter Air Tube Connector Silicone Massager	Air Tube Breast Shield Kit with back-flow protector Bottle Bottle Cover Nipple Bottle Cap Bottle Disk Bottle Stand Adapter B-Connector Micro USB Cable Silicone Massager Micro USB Jack Cover
Backflow Protection	Yes (Milk is prevented from entering the tubing)	Yes (Milk is prevented from entering the tubing)
Cleaning Method	- Breast pump:	- Breast pump:

	Proposed Device	**Predicate Device**
	Wipe with clean, damp cloth - Breast Shield Kit: Boiling water	Wipe with clean, damp cloth - Breast Shield Kit: Boiling water

The indications for use statement of the subject device is unchanged from the predicate device; accordingly, the subject and predicate device have the same intended use. The subject and predicate device have similar technological characteristics, and the differences in technological characteristics do not raise different questions of safety or effectiveness.

Summary of Performance Testing

The following performance data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The OPERA & OPERA eco comply with the electrical safety and electromagnetic compatibility requirements established by the standards.

- Electrical Basic Safety and Essential Performance requirements in accordance with IEC 60601-1:2005/AM1:2012
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014
- Medical electrical equipment and medical electrical systems used in the home healthcare environment in accordance with IEC 60601-1-11:2015

2) Software Validation

The OPERA & OPERA eco have a MODERATE level of concern. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- "The content of premarket submissions for software contained in medical devices, published on May 11, 2005"

3) Biocompatibility

The OPERA & OPERA eco were assessed for biocompatibility per ISO 10993.

4) Performance testing

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.

Conclusion

The performance testing demonstrate that the OPERA & OPERA eco (K190810) are substantially equivalent to the predicate device, MINUET LCD, MINUET LCD eco (K180075).