February 6, 2025

Unimom.Co
Yeong-Bin Chon
Quality Management Representative
110-19, Gajangsaneopseobuk-ro
Osan-si, 18102
KOREA,SOUTH

Re: K242111
Trade/Device Name: VIVACE
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: December 10, 2024

Dear Yeong-Bin Chon:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242111

Device Name
VIVACE

Indications for Use *(Describe)*
The VIVACE is a powered breast pump intended to express and collect milk from the breasts of lactating women. The VIVACE is intended for single user and multiple users in home and healthcare environments.

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
K242111

1. Submitter Information

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2. Correspondent Information

Contact: Jong-Hyun Kim
CEO
Firm: Global Medical Standard Consulting Co. Ltd.
Phone: + 82-02-2135-9540
Email: fda@gmsc.kr

3. Date prepared: February 6, 2025

4. Device Information

Device Trade Name:	VIVACE
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

5. Predicate Device Information

Device Name:	OPERA
510(k) Number:	K190810
Manufacturer:	Unimom Co.

The **P**redicate Device has not been subject to a design-related recall.

6. Device Description

The VIVACE is a powered breast pump intended to express and collect milk from the breasts of lactating women. The device is intended for daily use in a home or health care and by a single user and multiple users. VIVACE is both AC- powered/battery-powered. The AC adapter uses a 100-240 VAC, 50/60Hz, 1.0A adapter, and the battery is a rechargeable Li-ion battery with specifications of 11.1V, 2200mAh, 24.4Wh. VIVACE is comprised of a flange, breast shield body, wide adapter, diaphragm, diaphragm cover, white valve, bottle cover, cap, disk, bottle, adapter, air tube, main body, nipple, and instruction manual. VIVACE supports a single pumping mode in which only one breast is expressed and a double pumping mode in which both breasts are expressed. The double pumping mode is divided into a synchronous mode that expresses at the same time and an alternative mode that expresses on both sides alternately. The vacuum provided covers a range of pressures from 50 mmHg to 280 mmHg, and cycle speeds (cycles/min) from 20 to 80 cycles/min. The device is provided non-sterile.

VIVACE includes the following features:

- LCD display shows the current status such as Mode (single, synchronous, alternative, massage, expression), cycle level and vacuum level of both breasts and mood light.
- Expression can be performed on one breast only (single mode), on both sides simultaneously (synchronous), or on both sides alternately (alternative).
- Expression mode: 1-12 level (50-280 mmHg), cycle speeds (28, 31, 34, 37, 40)
- Massage mode: 1-6 level (60-160 mmHg), cycle speeds (40, 50, 60, 70, 80)

The breast pump expresses breast milk by creating a seal around the nipple using a flange and applying and releasing suction to the nipple. The milk is collected in a milk collection container, which can be used for storage. To prevent milk from flowing into the vacuum system, a backflow protection membrane (diaphragm) physically separates the milk-contacting pathway from the vacuum system.

7. Indications for Use

The VIVACE is a powered breast pump intended to express and collect milk from the breasts of lactating women. The VIVACE is intended for single user and multiple users in home and healthcare environments.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

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

Table 1: Comparator Table for Subject, Predicate Device

	Subject Device K242111	Predicate Device K190810	Comparison
Product Name	VIVACE	OPERA, OPERA eco	Same
Product Code	HGX	HGX	Same
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	Same
Regulatory Class	Class II	Class II	Same
Patient Population	Lactating Women	Lactating Women	Same
Indications for Use	The VIVACE is a powered breast pump intended to express and collect milk from the breasts of lactating women. The VIVACE is intended for single user and multiple users in home and healthcare environments.	The OPERA & OPERA eco are multiple- user, powered breast pumps intended to express and collect milk from the breasts of lactating women.	**Similar**
Multiple user	Yes, Single and Multiple users.	Yes, Multiple users	Same
Pump Options	Single or Double	Single or Double	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Backflow Protection	Yes	Yes	Same
Mobile Application	No	No	Same
Indicators	Yes, LCD	Yes, LCD	Same
Expression pattern	2-Phase	2-phase	Same

Power supply	Li-ion battery: Rechargeable battery (11.1 V, 2200mAh, 24.4Wh) AC adapter: -Input: 100-240 VAC., 50/60 Hz, 1.0A -Output: 14.0Vd.c, 2.0A, 28.0W	Rechargeable Lithium polymer battery, 11.1 V, 2200mAh (Only for OPERA) AC/DC Adapter - Rated input: AC 100~240V, 50/60Hz Rated output: DC14V, 2A	**Similar**
Suction levels (massage)	60 – 160 mmHg, 6 levels	45-150mmHg, 5 Levels	**Different**
Suction levels (expression)	50 – 280 mmHg, 12 levels	90 - 280 mmHg, 8 Levels	**Different**
Cycles per minute (massage)	40-80 per minute, 5 levels	60 – 100 cycles/min, 5 levels	**Different**
Cycles per minute (expression)	28-40 per minute, 5 levels	26 – 42 cycles/min, 5 levels	**Different**
User Interface	LCD display for battery status, mode, and vacuum level. Button for on/off. Button for mode selection. Buttons to increase/decrease vacuum for each pump. Buttons for increase/decrease Cycle. Buttons to change mood light.	LCD Display Switch control - Power, Vacuum / Cycle Up or Down Mode switch	**Different**
Adjustable Suction Levels	Yes	Yes	Same
Pump type	Diaphragm	Diaphragm	Same

The indications for use of the subject and predicate device are similar, and they have the same intended use – for the expression and collection of milk from the breasts of lactating women. The subject and predicate devices have differences in their power supply, suction strengths, cycle speeds, and user interface. However, these differences do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the subject device met all design specifications to be considered substantially equivalent to the predicate device and reference device.

Biocompatibility

Per the 2023 FDA guidance document, Use of International Standard ISO 10993-1, "Biological evaluation of medical – Part 1: Evaluation and testing within a risk management process", the following tests were performed on the direct user contacting device materials:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2021)
- Irritation (ISO 10993-23:2021)

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

Electrical Safety

Testing was conducted in accordance with

- IEC 60601-1:2005 + A1:2012 + A2:2020 (3.2 Edition) *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,*
- IEC 60601-1-11:2015+A1:2020 (2.1 Edition) *Medical electrical equipment – Part 1-11: General*

requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment,

- IEC 62133-2 *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems.*

Electromagnetic Compatibility

Testing was conducted in accordance with

- IEC 60601-1-2:2014 + AMD 1:2021 *Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests*.

Software

Software was evaluated as recommended in the 2023 FDA guidance document, *Content of Premarket Submissions for Software Functions.*

Performance Testing

Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Vacuum level verification testing at each mode/cycle demonstrated that the devices meet mode/cycle specifications.
- Backflow protection testing was conducted to verify liquid does not backflow into the tubing.
- Use life testing was conducted to demonstrate that the device maintains its specifications throughout its proposed use life.
- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.
- Multiple user cross-contamination testing (via microbial tightness validation) was conducted to demonstrate the effectiveness of the diaphragm at preventing cross-contamination.

10. Conclusion

The results of the performance testing described above demonstrate that VIVACE is as safe and effective as the predicate device and reference device and supports a determination of substantial equivalence.