March 28, 2024

Unimom.Co
% Jong-Hyun Kim
CEO
Global Medical Standard Consulting Co., Ltd.
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Gyeonggi-do, 10543
KOREA, South

Re: K232047
Trade/Device Name: VIVACE
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: March 4, 2024
Received: March 4, 2024

Dear Jong-Hyun Kim:

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.

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,

Michael T. Bailey -S

For
Monica D. Garcia, Ph.D.
Assistant 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K232047

Device Name
VIVACE

Indications for Use *(Describe)*
The VIVACE is a powered breast pump to be used by lactating women to express and collect milk from their breast. The VIVACE is intended for a single user.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary
# K232047

**1. Submitter Information**

Applicant: Unimom Co.
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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:** March 28, 2024

**4. Device Information**

| | |
|---|---|
| Device 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: | Class II |

**5. Predicate Device Information**

| | |
|---|---|
| Device Name: | OPERA, OPERA eco |
| 510(k) Number: | K190810 |
| Manufacturer: | Unimom Co. |

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

**6. Device Description**

VIVACE is an electric breast pump intended to express and collect milk from the breasts of lactating women. The device is intended for daily use in a home environment by a single user. VIVACE is both AC-powered/battery-powered. The AC adapter uses a 100-240 V a.c, 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.

Unimom VIVACE provides 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 physically separates the milk-contacting pathway from the vacuum system.

## 7. Indications for Use

The VIVACE is a powered breast pump to be used by lactating women to express and collect milk from their breast. The VIVACE is intended for a single user.

## 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 and predicate device.

**Table 1: Comparator Table for Subject and Predicate Devices**

| | **Subject Device K232047** | **Predicate Device K190810** | **Comparison** |
|---|---|---|---|
| Product Name | VIVACE | OPERA, OPERA eco | - |
| 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 to be used by lactating women to express and collect milk from their breast. The VIVACE is intended for a single user. | The OPERA & OPERA eco are multiple user, powered breast pumps intended to express and collect milk from the breasts of lactating women | **Different. The predicate device can be used by multiple users, while the subject device is only for use by a single user. This difference does not represent a new intended use, as both are used to express and collect milk from the** |

| | | | |
|---|---|---|---|
| | | | **breasts of lactating women.** |
| Pump Options | Single or Double | Single or Double | **Same** |
| Suction modes | Massage, expression | Massage, expression | **Same** |
| Backflow Protection | Yes | Yes | **Same** |
| Indicators | Yes, LCD | Yes, LCD | **Same** |
| Single User | Yes | No, Multiple users | **Different**<br>**The subject device is only for use by a single user. This difference does not raise different questions of safety and effectiveness.** |
| Power supply | Li-ion battery: Rechargeable battery (11.1 V, 2200mAh, 24.4Wh)<br><br>AC adapter:<br>-Input: 100-240 Va.c., 50/60 Hz, 1.0A<br>-Output: 14.0 Vd.c, 2.0A, 28.0W | Li-ion battery:<br>Rechargeable Lithium Polymer battery (only for OPERA)<br><br>AC/DC Adapter<br>- Rated input: AC 100~240V, 50/60Hz<br>- Rated output: DC14V, 2A | **Same** |
| Suction levels (massage) | 60 – 160 mmHg, 6 levels | 45-280 mmHg (510(k) Summary doesn't specify between massage and expression modes), 5 levels | **Different.**<br>**Differences in massage suction levels do not raise different questions of safety and effectiveness.** |
| Suction levels (expression) | 50 – 280 mmHg, 12 levels | 45-280 mmHg (510(k) Summary doesn't specify between massage and expression modes), 8 levels | **Different.**<br>**Differences in expression suction levels do not raise different questions of safety and effectiveness.** |
| Cycles per minute (massage) | 40-80 cycles per minute, 5 levels | 60-100 cycles per minute, 5 levels | **Different.**<br>**Differences in massage cycle speeds do not raise different questions of safety and effectiveness.** |
| Cycles per minute (expression) | 28-40 cycles per minute (synchronous), 44-60 cycles per minute (alternative), 5 levels | 26-42 cycles per minute, 5 levels | **Different.**<br>**Differences in expression cycle speeds do not raise different questions of safety and effectiveness.** |
| User Interface | LCD display for battery status, mode, and vacuum level.<br>Button for on/off.<br>Button for selection mode. | Switch control<br>- Power, Vacuum / Cycle Up or Down<br>- Mode switch | **Similar** |

| | | | |
|---|---|---|---|
| | Buttons for increase/decrease vacuum for each pump.<br>Buttons for increase/decrease Cycle.<br>Buttons for change mood light. | LCD Display | |
| Adjustable Suction Levels | Yes | Yes | **Same** |
| Pump type | Diaphragm | Diaphragm | **Same** |

The indications for use of the subject and predicate device are not identical as shown in the table above; however, they have the same intended use (i.e., for collection of breast milk from the breasts of lactating women).

The subject and predicate devices have similar technological features, including pumping options, control mechanism, user interface, backflow protection, and device indicators. However, as shown in the table above, there are technological differences between the subject and predicate device, including different vacuum and cycle specifications and vacuum levels. The different technological characteristics of the subject device, as compared to the predicate device, 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.

**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,* and 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.

**10. Conclusion**

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