August 21, 2026

Cimilre Co., Ltd.
% Jong-Hyun Kim
CEO
GMSC Co., Ltd.
66, Cheongcho-Ro, Deogyang-Gu, Goyang-Si
Gyeonggi-Do, 10543
Republic Of KOREA

Re: K260643
Trade/Device Name: Cimilre Dual Max
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 27, 2026
Received: February 27, 2026

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: The Center for Devices and Radioloical Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260643

Device Name
Cimilre Dual Max

Indications for Use *(Describe)*
The Cimilre Dual Max is a powered breast pump intended to express and collect milk from the breasts of lactating women. The Cimilre Dual Max is intended for multiple users and single user 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 – K260643

1. Submitter Information

Applicant: CIMILRE CO.,LTD
Address: 97-14, Seongnam-ro, Mokcheon-eup, Dongnam-gu, Cheonan-si, Chungnam, Republic of Korea [Zip. 31234]

2. Correspondent Information

Contact: Misun Na
Phone: + 82-41-5540942
Email: msna@cimilre.kr

3. Date prepared:

August 21, 2026

4. Device Information

Device Trade Name:	Cimilre Dual Max
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:	VIVACE
510(k) Number:	K242111
Manufacturer:	Unimom Co.

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

6. Device Description

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

The Cimilre Dual Max is a battery-powered breast pump that operates using an internal rechargeable lithium-polymer battery (11.1 V, 2000 mAh). The battery is charged via an external AC-to-DC power adapter with an input rating of AC 100–240 V, 50/60 Hz, 0.8 A and a DC output of 12 V, 2 A (maximum).

The device consists of a main body and removable components for breast milk expression and collection.

Two types of breast shield kits are provided: a Hands-Free Kit (HT5) and a Standard Kit (Wide). The Hands-Free Kit (HT5) includes an HT5 breast shield, breast shield cover, diaphragm, insert, valve, bottle, disk, hose tip, bottle cap, nipple, screw, tubing, and adapter. The Standard Kit (Wide) includes a backflow protection assembly (upper case, lower case, and diaphragm), along with a

standard breast shield, valve, bottle, disk, bottle cap, nipple, screw, tubing, and adapter. An instruction manual is provided for proper assembly, operation, cleaning, and maintenance.

The Cimilre Dual Max supports both single and double pumping operation.
In single mode, breast milk is expressed from one breast, and in double mode, breast milk is expressed from both breasts simultaneously (synchronous mode). The device provides adjustable vacuum levels suitable for breast milk expression.

In expression mode, the vacuum level is adjustable from approximately 80 mmHg to 280 mmHg across 12 selectable levels, and in massage mode, from approximately 80 mmHg to 160 mmHg across 5 selectable levels. The device also offers multiple selectable cycle speeds, ranging from approximately 30 to 54 cycles per minute in expression mode and from approximately 65 to 95 cycles per minute in massage mode, each across 7 selectable levels.
The device is supplied non-sterile.

The device generates suction pressure through an internal motor-driven pump, which is transmitted to the breast through the breast shield to enable milk expression.
Expressed milk is collected in a removable milk collection container.

All milk-contacting components are compliant with 21 CFR 174–179.

7. Indications for Use

The Cimilre Dual Max is a powered breast pump intended to express and collect milk from the breasts of lactating women. The Cimilre Dual Max is intended for multiple users and single user 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 and predicate device.

Table 1: Comparator Table for Subject, Predicate Device

	Cimilre Dual Max K260643 Subject Device	**VIVACE K242111 Predicate Device**
Product Name	Cimilre Dual Max	VIVACE
Product Code	HGX	HGX
Regulation Number	21 CFR 884.5160	21 CFR 884.5160
Regulatory Class	Class II	Class II
Patient Population	Lactating Women	Lactating Women

Indications for Use	The Cimilre Dual Max is a powered breast pump intended to express and collect milk from the breasts of lactating women. The Cimilre Dual Max is intended for multiple users and single user in home and healthcare environments.	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.
Multiple user	Yes, Single and Multiple users.	Yes, Single and Multiple users.
Pump Options	Single or Double	Single or Double
Backflow Protection	Yes	Yes
Mobile Application	No	No
Indicators	Yes, LCD	Yes, LCD
Power supply	Li-Polymer Rechargeable battery 11.1V 2000mAh Adapter: -Input: AC 100-240V, 50/60Hz, 0.8A -Output: DC 12V 2A(MAX)	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
Suction levels (massage)	80 – 160 mmHg, 5 levels	60 – 160 mmHg, 6 levels
Suction levels (expression)	80 – 280 mmHg, 12 levels	50 – 280 mmHg, 12 levels
Cycles per minute (massage)	65-95 per minute, 7 levels	40-80 per minute, 5 levels
Cycles per minute (expression)	30-54 per minute, 7 levels	28-40 per minute, 5 levels
Adjustable Suction Levels	Yes	Yes
Pump type	Diaphragm	Diaphragm

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 technological differences in their power supply, suction strengths, cycle speeds, and user interface. However, these differences do not raise different questions of safety and effectiveness and can be evaluated through performance testing.

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 results of these studies demonstrated that the device is non-cytotoxic, non-sensitizing, and non irritating, supporting the biological safety of the device for its intended use.

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.*

The results of this testing demonstrate that the device meets applicable requirements for electrical safety, battery safety, and suitability for use in the home healthcare environment, with no evidence of unacceptable risk or degradation in performance under the tested conditions.

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*. The results demonstrate that the device complies with applicable emissions and immunity requirements, and that essential performance is maintained without unacceptable degradation during exposure to electromagnetic disturbances.

Software

Software was evaluated at the Basic Documentation level as recommended in the 2023 FDA guidance document "*Content of Premarket Submissions for Device Software Functions*." The software documentation included the software description, hazard analysis, verification and validation testing, and revision history, consistent with expectations for a Basic Documentation level device. The results of software verification and validation demonstrate that the software performs as intended, with no unresolved anomalies that would impact device safety or effectiveness.

Performance Testing

Performance testing was performed to confirm that the Subject Device complies with its defined design specifications and performs consistently with its intended purpose. The following verification and validation activities were conducted:

- Vacuum Performance Verification: Testing was performed across each operating mode and cycle configuration to confirm that generated suction pressures meet the specified design output ranges.
- Backflow Prevention Evaluation: Verification testing demonstrated that the device design effectively prevents liquid ingress or reverse flow into the tubing pathway under normal and foreseeable use conditions.
- Cross-Contamination Evaluation: Microbiological testing was conducted under simulated worst-case operating conditions to evaluate the potential transfer of microorganisms to

reusable shared and non–milk-contacting components during intended multi-user use. The testing demonstrated no detectable microbial transfer to the evaluated shared components, supporting the effectiveness of the device's backflow protection design in mitigating cross-contamination.

- Life cycle performance test: Simulated use-life testing was conducted to verify that device performance remains within specification throughout the labeled service life.
- Battery Performance Testing: Battery validation confirmed reliable operation during typical usage conditions and demonstrated continued functionality over the expected battery life.

The results of these tests demonstrate that the device meets its performance specifications, maintains functional integrity over its intended use life, and performs as intended without evidence of degradation that would impact safety or effectiveness

10. Conclusion

The results of the performance testing described above demonstrate that the Cimilre Dual Max is as safe and effective as the Predicate Device and supports a determination of substantial equivalence.