December 23, 2022

Cimilre Co., Ltd.
℅ Dave Yungvirt
Most Responsible Person
Third Party Review Group, LLC
25 Independence Blvd.
Warren, NJ 07059

Re: K221708
Trade/Device Name: CIMILRE Free-T2 Plus / CIMILRE Free-T2
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: October 22, 2022
Received: October 25, 2022

Dear Dave Yungvirt:

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,

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221708

Device Name
CIMILRE Free-T2 Plus / CIMILRE Free-T2

Indications for Use *(Describe)*
CIMILRE Free-T2 Plus / CIMILRE Free-T2 is an electrically powered breast pump intended to express and collect breastmilk from lactating women. The device is intended to be used by 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary – K221708

## 1. Submitter Information

Applicant: Cimilre Co., Ltd.
Address: 97-14, Seongnam-Ro, Mokcheon-Eup,
Dongnam-Gu Cheonan-Si,
Chungcheongnamdo, Republic of Korea
31234
.

## 2. Correspondent Information

Contact: Byung Hoon Jeon
Phone: +82-41-553-0941
Email: bhjeon@cimilre.kr

## 3. Date prepared: December 22, 2022

## 4. Device Information

| | |
|---|---|
| Device Name: | CIMILRE Free-T2 Plus / CIMILRE Free-T2 |
| 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: | Cimilre F1, Cimilre S3 |
| 510(k) Number: | K162870 |
| Manufacturer: | Cimilre Co., Ltd. |

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

## 6. Device Description

The Cimilre Free-T2 Plus and Cimilre Free-T2 are electrically powered wearable single breast pumps consisting of the following key components: a breast shield, valve, milk bottle, milk bottle cap, silicone backflow protector, nipple, locking ring, and C-type USB cable. The main body is powered by a rechargeable internal battery facilitating a motor and solenoid valve to generate suction pressure for breast pumping. The device is electronically operated with a microprocessor controlled by integrated software to provide a range of adjustable vacuum pressure and cycle rates. Pumping can be performed on one breast (single pumping) in wearable mode. The user interface allows the user to switch from massage to expression mode and control the vacuum levels within those modes. Both massage and expression mode consist of 12 total vacuum levels (5 massage, 7 expression). Both models are capable of providing vacuum levels from 50-130 mmHg with cycling rates from 55-70 cycles per minute in massage mode and vacuum levels from 150-280 mmHg with cycling rates from 27-51 cycles per minute in expression mode. The subject devices are powered by a 3.7 V 1200 mA internal rechargeable lithium-ion polymer battery. The motor unit operates on embedded software. The Free-T2 Plus model can communicate wirelessly via Bluetooth with smartphone devices. Software updates by end-users are not supported. The subject devices are for repeated use by a single user in a home environment. The devices are provided not sterile.

The breast pump expresses by creating a seal around the nipple using the breast shield 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.

All other components (i.e., motor unit) of the subject device are not in contact with the breast.

The motor unit operates on a rechargeable battery and does not function when charging. The rechargeable battery can be charged from the external USB adapter if the motor unit is not in operation.

The subject device components are made of the following materials:

- Motor unit
- Backflow protector, valve, breast shield insert, nipple: Silicone
- Breast Shield, milk bottle (and cap), locking ring, disc: Propylene Ethylene Copolymer

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

## 7. Indications for Use

CIMILRE Free-T2 Plus / CIMILRE Free-T2 is an electrically powered breast pump intended to express and collect breastmilk from lactating women. The device is intended to be used by 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**

| | **CIMILRE Free-T2 Plus<br>CIMILRE Free-T2<br>K221708<br>Subject Device** | **CIMILRE F1<br>CIMILRE S3<br>K162870<br>Predicate Device** | **Comparison** |
|---|---|---|---|
| Product Name | Cimilre Co., Ltd. | Cimilre Co., Ltd. | **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 (single user) | Lactating Women (single user) | **Same** |
| Indications for Use | CIMILRE Free-T2 Plus / CIMILRE Free-T2 is an electrically powered breast pump intended to express and collect breastmilk from lactating women. The device is intended to be used by a single user. | The CIMILRE F1 and CIMILRE S3 are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women. | **Different** |
| Pump Options | Single | Single | **Same** |
| Cycling control mechanism | Microcontroller | Microcontroller | **Same** |
| Backflow Protection | Yes | Yes | **Same** |
| Suction Modes | Massage Mode and Expression Mode | Massage Mode and Expression Mode | **Same** |

| | | | |
|---|---|---|---|
| Suction levels | 12 (Massage: 1-5 levels; Expression: 6-12 levels) | CIMILRE F1: (Massage: 5 levels; Expression: 10 levels)<br>CIMILRE S3: (Massage: 5 levels; Expression: 12 levels) | **Different:** The difference in available levels do not raise different questions of safety and effectiveness as these differences were verified by the performance testing below. |
| Adjustable suction levels | Yes | Yes | **Same** |
| Vacuum range: Massage | -50 to -130 (±20) mmHg | 40 - 280 mmHg | **Different** |
| Vacuum range: Expression | -150 to -280 (±20) mmHg | 40 - 280 mmHg | **Different** |
| Cycle Speed: Stimulation | 55 to 70 (±3) cycles/minute | CIMILRE S3: 30 - 60 Cycles/min<br>CIMILRE F1: 25 - 60 Cycles/min | **Different** |
| Cycle Speed: Expression | 27 to 51 (±3) cycles/minute | CIMILRE S3: 30 - 60 Cycles/min<br>CIMILRE F1: 25 - 60 Cycles/min | **Different** |
| Controls | 3 buttons<br>On/Off button;<br>Increase/decrease vacuum button; | 4 Buttons (CIMILRE F1); 7 Buttons (CIMILRE S3)<br>On/Off button;<br>Mode selection<br>Increase/decrease vacuum button;<br>Increase/Decrease cycle level (CIMILRE S3 only);<br>LED on-Off (CIMILRE S3 only) | **Similar:** The differences in user interface do not raise different questions of safety and effectiveness. |
| Wireless connectivity | Yes, Bluetooth | No | **Different:** The differences in wireless connectivity functionality do not raise different questions of safety and effectiveness as these differences were substantiated by the performance testing below. |
| Power Supply | 3.7 VDC Li-Ion Battery | 12 VDC Li-Ion Battery | **Same** |
| Indicators | Yes, FND | Yes, LCD and LED (CIMILRE S3) | **Similar:** The differences in status indicators do not raise different questions of safety and effectiveness. |
| Materials | Motor unit,<br>Backflow protector, valve, breast shield insert, nipple: Silicone;<br>Breast Shield, milk bottle (and cap), locking ring, disc: Propylene Ethylene Copolymer | Breast shield set is made of Silicone, PP, and Silicone hardness 60 L.S.R | **Different:** The differences in material composition do not raise different questions of safety and effectiveness as these differences were substantiated by the biocompatibility performance testing below. |

The indications for use of the subject and predicate device are similar, with minor differences related to intended use population (single vs. multiple users). The subject and predicate device have the same intended use – to express and collect breastmilk from lactating women.

The subject and predicate devices have similar technological features, including device design, overall vacuum pressure range, materials, and wearable functionality. The subject and predicate device have different technological characteristics, including different vacuum level and cycle speed specifications. The

different technological characteristics of the subject device do not raise different questions of safety and effectiveness, as these differences can be assessed by the performance testing outlined below.

**9. Summary of Non-Clinical Performance Testing**

The following tests were performed to demonstrate that the subject device met the applicable design and performance requirements.

**Biocompatibility**

Biocompatibility studies, including Skin Irritation Testing, Cytotoxicity, and Skin Sensitization testing were performed in accordance with the 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process"* and ISO 10993- 1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Skin Sensitization (ISO 10993-10:2010)
- Skin Irritation (ISO 10993-10:2010)

The testing supports the biocompatibility of the device. The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

**Electrical Safety**

Testing was conducted in accordance with AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD), IEC 62133-2:2017, 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, and IEC 60601-1-11:2015 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.

**Electromagnetic Compatibility**

Testing was conducted in accordance with IEC 60601-1-2:2014 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 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

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 testing described above demonstrate that the CIMILRE Free-T2 Plus/CIMILRE Free-T2 is as safe and effective as the predicate device and supports a determination of substantial equivalence.