DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 7, 2017

Cimilre Co., Ltd.
Ko Bong Jae
R & D General Manager
#201, 202, Sagimakgol-ro 148Jungwon-gu
Seongnam-si, Gyeonggi-do 13207
Korea

Re: K162870
Trade/Device Name: CIMILRE F1 and CIMILRE S3
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: January 23, 2017
Received: January 24, 2017

Dear Ko Bong Jae:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162870

Device Name
CIMILRE F1 and CIMILRE S3

Indications for Use *(Describe)*
The CIMILRE F1 and CIMILRE S3 are single-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.

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."

#201, 202, Sagimakgol-ro 148, Jungwon-gu Seongnam-si, Gyeonggi-do, Korea (Zip.13207)
Tel. +82-31-723-0941 / Fax. +82-31-723-0940

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

February 17, 2017

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: CIMILRE CO., LTD.
- Address: #201, 202, Sagimakgol-ro 148, Jungwon-gu Seongnam-si, Gyeonggi-do, Korea (Zip.13207)
- Contact Name: Ko Bong Jae / General Manager
- Telephone No.: +82-31-723-0941
- Fax No.: +82-31-723-0940
- Email Address: bjko@cimilre.kr
- Registration No.: In process

3. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

Trade/Device Name	CIMILRE F1 and CIMILRE S3
Common Name	Powered breast pump
Regulation Number	21 CFR 884. 5160
Regulation Name	Powered breast pump
Regulation Class	Class II
Product Code	HGX
Product Code Name	Pump, Breast, Powered

cimilre
#201, 202, Sagimakgol-ro 148, Jungwon-gu Seongnam-si, Gyeonggi-do, Korea (Zip.13207)
Tel. +82-31-723-0941 / Fax. +82-31-723-0940

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

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

- 510(k) Number: K150476
- Applicant: Uzinmedicare Co.
- Trade/Device Name Spectra S1 Plus and Spectra S2 Plus
- Regulation Number 21 CFR 884. 5160
- Regulation 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.

5. Description of the Device [21 CFR 807.92(a)(4)]

This device is designed to express and collect milk from the breast of a lactating woman. When operated in mode, the device generates the pressure through the interaction of the diaphragm pump and the solenoid electric mechanism. The device adopts the microprocessor that can control the procedure to set and adjust the vacuum levels and cycles of Massage Mode and Express Mode.

Two Modes are pre-programmed with variable vacuum levels and cycle rates (pump speed). The device is capable of providing vacuum levels from 40 to 280 mmHg with cycle rates up to 60 cycles per minute.

The CIMLIRE F1 and S3 are intended for daily use in a home (or similar environment such as an office) to supplement breastfeeding by a single user.

The CIMILRE F1 is powered by a 12 VDC adaptor or rechargeable lithium battery. The CIMILRE S3 is powered only by a 12VDC adaptor.

Accessories for CIMILRE F1 and CIMILRE S3 are as follows:

1) Breast Shield Set
   (Tubing, Back-flow Protector, Breast Shield, Silicone Valve, Bottle, Bottle cover, Nipple, Bottle Cap, Disk)
   The Breast Shield Set is made of Silicone, Polypropylene and silicone hardness 60 L.S.R

2) Adaptor (DC 12 V, 2 A)

The CIMILRE F1, CIMILRE S3 pump provides the following user features:

1) Two Modes are provided as follows:
   - Massage Mode: suction pattern with fast cycles and low vacuum to start milk flowing
   - Expression Mode: suction pattern with slower cycles and higher vacuum to express milk.
2) Diaphragm pump design with solenoid electric mechanism.
3) Adjustment of vacuum level/cycles
4) LCD display, for user assistance/device status.
5) Option of either single or double breast pumping.

For a full list of device specifications, please see the Table 1. Comparison of Proposed Device to Predicate Device.

6. Indications for use [21 CFR 807.92(a)(5)]

The CIMILRE F1 and CIMILRE S3 are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.

cimilre
#201, 202, Sagimakgol-ro 148, Jungwon-gu Seongnam-si, Gyeonggi-do, Korea (Zip.13207)
Tel. +82-31-723-0941 / Fax. +82-31-723-0940

7. Determination of Substantial Equivalence

Summary of technological characteristics of the device compared to the predicate device. [21 CFR 807.92(a)(6)]

The indications for use of CIMILRE F1 and CIMILRE S3 are the same as the predicate devices. Both the subject and predicate devices have the same intended use.

The subject and the predicate device generate vacuum in a similar manner.

A microprocessor controlled DC motor provides motive force to create volumetric expansion and vacuum. (Pump type: Diaphragm)

The CIMILRE F1 and CIMILRE S3 are substantially equivalent to the legally marketed predicate devices with respect to indications for use and technology characteristics. The table below presents comparisons for each device:

[Table 1. Comparison of Proposed Device to Predicate Device]

	Proposed Device	Predicate Device
Product Name	CIMILRE F1 and CIMILRE S3	Spectra S1 Plus and Spectra S2 Plus
510(k) Number	K162870	K150476
Manufacturer	CIMILRE Co. Ltd.	Uzinmedicare Co.
Product Code	HGX	HGX
Device Class	II	II
Indications for Use	The CIMILRE F1 and CIMILRE S3 are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.	The Spectra S1 Plus and Spectra S2 Plus are single-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.
Intended use population	Single-user	Single-user
Intended use environment	Home environment	Home environment
Specifications		
Power source (Adaptor)	AC/DC Converter (12 VDC)	AC/DC Converter (12 VDC)
Power source (Battery)	Rechargeable Lithium Polymer Battery	Rechargeable Lithium Ion Battery (only for Spectra S1 Plus)

cimilre
#201, 202, Sagimakgol-ro 148, Jungwon-gu Seongnam-si, Gyeonggi-do, Korea (Zip.13207)
Tel. +82-31-723-0941 / Fax. +82-31-723-0940

	Proposed Device		Predicate Device
	(only for CIMILRE F1)		
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	CIMILRE F1	Massage Mode: - 5 levels Expression Mode: - 10 Levels	Massage Mode: 5 levels Expression Mode: 12 Levels
	CIMILRE S3	Massage Mode: - 5 levels Expression Mode: - 12 Levels	
Vacuum Strength	40 - 280 mmHg		50 – 280 mmHg
Cycle Range	25 - 60 Cycles/min.(F1) 30 - 60 Cycles/min.(S3)		38 - 70 cycles/min
User Interface	Tact switch control - Power, Vacuum/Cycle Up or Down - Mode switch LCD Display		Tact switch control - Power, Vacuum/Cycle Up or Down - Mode switch LCD Display
Accessories	Tubing, Back-flow Protector Breast Shield Silicone Valve Bottle Bottle cover Nipple Bottle Cap Disk Adaptor		Tubing, Back-flow Protector Breast Shield Valve Bottle Bottle cover Nipple Bottle Cap Disk Adaptor
Backflow Protection	Yes (milk is prevented from entering the tubing.)		Yes (milk is prevented from entering the tubing)
Cleaning Method	- Breast pump: wipe with clean, damp cloth - Breast Shield set: Boiling water		- Breast pump: wipe with clean, damp cloth - Breast Shield set: Boiling water

The table also provides rationale for a little difference in support of substantial equivalence to the Predicate devices

[Table 2. Little difference with Predicate Device.]

Justification to Support Substantial Equivalence
The subject device has a different user interface,appearance, battery type, vacuum levels and cycle speeds. These differences do not alter the intended use of the device from that of the predicates. In addition, these technological differences do not raise different questions of safety and effectiveness

Non-Clinical Test Summary

The CIMILRE F1 and CIMILRE S3 complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and usability. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

   The CIMILRE F1 and CIMILRE S3 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/AMD1:2012+ National Deviations for US
   - Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2007 (Third Edition)
   - Medical electrical equipment and medical electrical systems used in the home healthcare environment in accordance with IEC 60601-1-11:2010

2) Software Validation

   The CIMILRE F1 and CIMILRE S3 contain MODERATE level of concern software as firmware. 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," issued May 11, 2005.

3) Biocompatibility

Biocompatibility of the devices was demonstrated by the following testing:

- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: tests for irritation and skin sensitization

The test results demonstrated that the subject device is non-cytotoxic, non-irritating and non-skin sensitizing.

4) Performance test

Performance of the devices was demonstrated by the following tests:

- Vacuum Strength Test
- Cycle Range Test
- Battery Operating Time

The test results demonstrate that the CIMILRE F1 and CIMILRE S3 met predefined acceptance criteria..

Clinical Test Summary

Clinical testing was not required to demonstrate the substantial equivalence of the CIMILRE F1 and CIMILRE S3 breast pumps to its predicate device.

8. Conclusion [21 CFR 807.92(b)(3)]

The CIMILRE F1 and CIMILRE S3 have the same intended use and similar technological characteristics to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness. In addition, performance testing conducted demonstrate that the subject devices are as safe and effective as the predicate. Therefore, the subject devices are substantially equivalent to the predicate.