March 6, 2021

Credo
% Dongha Lee
Regulatory Affairs Consultant
KMC, Inc.
Room no. 904, 27, Digital-ro 27ga-gil, Guro-gu
Seoul, 08375
Republic of Korea

Re: K201581
Trade/Device Name: CPR Band
Regulation Number: 21 CFR 870.5210
Regulation Name: Cardiopulmonary Resuscitation (CPR) Aid
Regulatory Class: Class II
Product Code: LIX
Dated: June 8, 2020
Received: June 11, 2020

Dear Dongha Lee:

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,

Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201581

Device Name
CPR BAND (Model: CREDO-CB, CREDO-CB-MO)

Indications for Use *(Describe)*
The CPR BAND is used as a guide in administering cardiopulmonary resuscitation (CPR) to a suspected sudden cardiac arrest (SCA) victim at least 8 years old.

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

This summary of 510(k) –safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: June 08, 2020

1. INFORMATION

1.1 Submitter Information

- Submitter Name: CREDO Ltd.
- Address
  : #302, 86, Baeul-ro, Wonju-si, Gangwon-do, 26465, Republic of Korea
- Telephone Number: +82-33-766-8901 ▪ Fax: +82-33-766-8902

1.2 First Contact Person

- Name: DongHa Lee (Consultant / KMC, Inc.)
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- Telephone Number: +82-70-8965-5554 ▪ Fax: +82-2-2672-0579
- E-mail: milly@kmcerti.com

2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name: CPR BNAD (Model: CREDO-CB, CREDO-CB-MO)

2.2 Common Name: Cardiopulmonary resuscitation (CPR) aid

2.3 Classification Name: Aid, Cardiopulmonary Resuscitation

2.4 Product Code: LIX

2.5 Classification Regulation: 21CFR 870.5210

2.6 Device Class: Class II (Special Control)

2.7 Classification Panel: Cardiovascular

3. PREDICATE DEVICE

Predicate Device	
Manufacturer	Laerdal Medical AS
Device Name (Trade Name)	CPRmeter 2 CPR Feedback Device
510(k) Number	K173886

4. SUBJECT DEVICE DESCRIPTION

The CPR BAND is a small, lightweight device that uses rechargeable batteries and is worn on the wrist. This device is designed for first aid personnel trained in CPR and use of the CPR BAND. The CPR BAND (Model: CREDO-CB) provides real-time information about chest compression according to the latest CPR guideline when CPR is performed on patient who is estimated a sudden cardiac arrest (SCA). This device displays CPR feedback indicator for the chest compression depth. It guides chest compression rhythm through sound and indicates the total chest compression time and number of chest compression.

The CPR BAND is a device that provides Bluetooth function. It can transmit CPR record and confirm information on the mobile application of the smart device in order to training CPR Skill for user via checking data. In the smart device that provides the wireless communication function by receiving information provided by the CPR BAND, it can display the pressure axis angle, pressure axis average value, compression depth average value, compression rhythm average value, and chest compression graph which are not displayed on the CPR BAND.

The device provides other functions on the user's wrist while waiting without CPR. The time, step count, movement distance and calorie consumption function are displayed.

5. Principle Operation

It is intended to wear it on the responder’s wrist during CPR. The CPR BAND is intended for use by responders who have been trained in CPR and use of the CPR BAND. When placed on the bare chest of a suspected SCA victim, the CPR BAND provides real-time feedback on CPR compressions in accordance with current CPR guidelines. The CPR BAND measures the chest compression depth during CPR via the built-in accelerometer and displays it on the LED. After CPR, the measured data is temporarily stored in the CPRBAND and transmitted to the application via the Bluetooth interface in order to training CPR Skill for user via checking data. In the application, detailed data information such as compression depth and compression rhythm can be checked.

6. INTENDED USE

The CPR BAND is used as a guide in administering cardiopulmonary resuscitation (CPR) to a suspected sudden cardiac arrest (SCA) victim at least 8 years old.

7. SUBSTANTIAL EQUIVALENCE

-		Subject Device	Predicate Device
Manufacturer		CREDO Ltd.	Laerdal Medical AS
Device Name		CPR BAND	CPRmeter 2
510(k) Number		K201581	K173886
Regulation Number		21CFR 870.5210	21CFR 870.5210
Regulation Name		Cardiopulmonary Resuscitation (CPR) Aid	Cardiopulmonary Resuscitation (CPR) Aid
Classification		Class II	Class II
Product Code		LIX	LIX
Indications for Use		The CPR BAND is used as a guide in administering cardiopulmonary resuscitation (CPR) to a suspected sudden cardiac arrest (SCA) victim at least 8 years old.	The CPRmeter 2 CPR Feedback Device is used as a guide in administering cardiopulmonary resuscitation (CPR) to a suspected sudden cardiac arrest (SCA) victim at least 8 years old.
Mechanism		When placed on the bare chest of a suspected SCA victim, the CPR BAND provides real-time feedback on CPR compressions in accordance with current CPR guidelines. The device measures the chest compression depth during CPR via the built-in accelerometer and displays it on the LED. The measured data is temporarily stored in the device and transmitted to the application via the Bluetooth interface. In the application, detailed data information such as compression depth and compression rhythm can be checked	When placed on the bare chest of a suspected SCA victim, the CPRmeter 2 provides real-time feedback on CPR compressions in accordance with current CPR guidelines. The device measures the chest compression depth during CPR via the built-in accelerometer and displays it on the LED. The measured data is temporarily stored in the device and transmitted to the application via the Bluetooth interface. In the application, detailed data information such as compression depth and compression rhythm can be checked
Design	**Dimension**	47.1mm x 21.1mm x 12mm	153mm x 64mm x 25mm
	Weight	11.0g	163g
	Measuring Methods	Accelerometer and force sensor	Accelerometer and force sensor
	Visual Output	Light emitting diodes	Light emitting diodes
	Auditory Output	Rhythm Guide	None
	Expected Service Life	3 years	2 years
	Battery	Lithium Battery	AA Battery
	Data Transfer	Bluetooth	Bluetooth

Real Time Compression Feedback	**Depth Target**	>50mm and <60mm	>50mm and <60mm
	Rate Target	100-120 per minute	100-120 per minute
Material		PC (Module Enclosure) URETHAN (BAND Part)	PC (Enclosure)

1) Same points between the subject device and the predicate device

Same Items	Description
Regulation Number	The proposed regulation number is “21CFR870.5210”. The Regulation is related to the Cardiopulmonary Resuscitation (CPR) Aid Device. It is the same point between the subject device (CPR BAND) and the predicate device (CPRmeter 2).
Regulation Name	The proposed regulation name is Cardiopulmonary Resuscitation (CPR) Aid in accordance with 21CFR870.5210. The subject device and predicate device are A CPR Aid device with feedback that provides real-time feedback to the rescuer regarding the quality of CPR being delivered to the victim, and provides either audio and/or visual information to encourage the rescuer to continue the consistent application of effective manual CPR in accordance with current accepted CPR guidelines. It is the same point between the subject device (CPR BAND) and the predicate device (CPRmeter 2).
Classification	In accordance with same regulation number (21CFR870.5210), FDA provide the regulatory classification. It is Class II and same point between the subject device (CPR BAND) and the predicate device (CPRmeter 2).
Product Code	The proposed product code of the subject device is “LIX”. It is the same product code with the predicate device.
Indication for use	In case of the indication for use, there is same overall with the subject device (CPR BAND) and the predicate device (CPRmeter 2). Both devices are used as a guide in administering cardiopulmonary resuscitation (CPR) to a

	suspected sudden cardiac arrest (SCA) victim at least 8 years old.
Mechanism	When placed on the bare chest of a suspected SCA victim, the both devices provide real-time feedback on CPR compressions in accordance with current CPR guidelines. Especially, both devices measure the chest compression depth during CPR via the built-in accelerometer and displays it on the LED. In addition, the measured data is temporarily stored in the device and transmitted to the application via the Bluetooth interface as the additionally function. In the application, detailed data information such as compression depth and compression rhythm can be checked. Its mechanism is same with subject device and predicate device.
Measuring Methods	Both devices measure the real-time compression feedback by using accelerometer and force sensor. Its point is same with subject device and predicate device.
Visual Output	Both devices have the LED Function as a visual output. Its point is same with subject device and predicate device.
Data Transfer	After compression, the measured data is temporarily stored in the device and transmitted to the application via the Bluetooth interface as the additionally function. Its point is same with subject device and predicate device.
Depth Target	In accordance with CPR guideline, CPR involves chest compressions between 5 cm (2.0 in) and 6 cm (2.4 in) deep. Its point is same with subject device and predicate device.
Rate Target	In accordance with CPR guideline, CPR involves chest compressions at a rate of at least 100 to 120 per minute. Its point is same with subject device and predicate device.

2) Different points between the subject device and the predicate device

Same Items	Description
510(k) Number	K number does not influence the safety and the performance of the subject device as well as does not influence substantial equivalence between the subject device the predicate device.
Dimension	Although the dimension of device is different between the subject device (CPR BAND) and the predicate device (CPRmeter 2), the subject device is verified by performance test. As a result, there are not any problems, which influence safety and performance of the subject device as well as critical fact to decision of the substantial equivalence between the subject device and the predicate device.
Weight	Although the weight of device is different between the subject device (CPR BAND) and the predicate device (CPRmeter 2), the subject device is verified by performance test. As a result, there are not any problems, which influence safety and performance of the subject device as well as critical fact to decision of the substantial equivalence between the subject device and the predicate device.
Auditory Output	Although the auditory output of device is different between the subject device (CPR BAND) and the predicate device (CPRmeter 2), the subject device is verified by performance test. As a result, there are not any problems, which influence safety and performance of the subject device as well as critical fact to decision of the substantial equivalence between the subject device and the predicate device.
Expected Service Life	Although the expected service life of device is different between the subject device (CPR BAND) and the predicate device (CPRmeter 2), the service life of subject device is decided to 3 years in accordance with the certified battery service life because the battery service life is critical component of CPR BNAD. As a result, there are not any problems, which influence safety and performance of the subject device as well as

	critical fact to decision of the substantial equivalence between the subject device and the predicate device.
Battery	The subject device (CPR BAND) should be used with lithium battery, but equivalent device (CPRmeter 2) should be sued with AA battery. Although the battery is different between the subject device and the equivalent device, the subject device battery shall be used with CE Marking in accordance with 2004/108/EC. As a result, there are not any problems, which influence safety and performance of the subject device as well as critical fact to decision of the substantial equivalence between the subject device and the predicate device.
Material	Material of device is different because there is no band on the equivalent device. Although the material is different between the subject device and the equivalent device, the subject device is verified with biocompatibility test in accordance with EN ISO 10993-1 for material safety. As a result, there are not any problems, which influence safety and performance of the subject device as well as critical fact to decision of the substantial equivalence between the subject device and the predicate device.

8. NON-CLINICAL DATA

8.1 Safety Test

1) Biocompatibility

The biocompatibility tests were performed to protect patients from undue risks arise from biological hazards associated with materials of manufacture and final device. The tests were performed in accordance with the following standards and FDA Guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

No.	Test Items	Standards
1	Cytotoxicity	ISO 10993-5:2009
2	Sensitization	ISO 10993-10:2010
3	Intracutaneous Reactivity Test	ISO 10993-10:2010

2) Electrical Safety and EMC

The electrical safety tests were performed to protect patients from undue risks arise from any hazards associated with final device. The tests were performed in accordance with the following standards.

No.	Test Items	Standards
1	General requirement for basic safety and essential performance	• IEC 60601-1:2005+A1:2012
2	General requirement for safety – Electromagnetic disturbances	• IEC 60601-1-2:2014
3	General requirement for safety – Medical electrical equipment used in the home healthcare environment	• IEC 60601-1-11:2015 • FDA Guidance (“Design Considerations for Devices Intended for Home Use”)
4	RoHS Test	• Directive 2011/65/EU • IEC 62321 Series
5	FCC	• FCC Part15 Subpart C 15.247 • Radio Frequency Wireless Technology in Medical Devices Guidance

8.2 Performance Test

The following tests were performed to assess effectiveness of the product performance. The tests were performed in accordance with following standards.

No.	Test Items	Standards
1	Compression Depth Indicator	Manufacturer SOP
2	Compression Rate Target	Manufacturer SOP
3	Compression Depth Target	Manufacturer SOP
4	Compression Count Target	Manufacturer SOP
5	Compression Time Target	Manufacturer SOP
6	Dimension Test	Manufacturer SOP

8.3 Usability V&V

The following tests were performed to assess effectiveness of usability of the device. The test was performed in accordance with following standards

No.	Test Items	Standards
1	General requirement for safety - Usability	• IEC 60601-1-6:2010+A1:2013 • IEC 62366:2007+A1:2014 • FDA Guidance ("Applying Human Factors and Usability Engineering to Medical Devices")

8.4 Software

The following tests were performed to assess effectiveness of software of the device. The test was performed in accordance with following standards.

No.	Test Items	Standards
1	General requirement for safety – Programmable electrical medical systems (PEMS)	• IEC 62304:2006/A1:2015 • FDA Guidance ("Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices")

9. CONCLUSION

Under the comparing substantial equivalence between the subject device and the predicate device, there are the same points such as general information, some technical and material information. Although there are some differences, the safety and performance test reports support that the subject device is substantially equivalent to the predicate device.

In this regard, we conclude that the subject device is substantially equivalent to the predicate device.