December 17, 2018

Laerdal Medical AS
% Dan Dillon
Senior Regulatory Scientist
MED Institute Inc.
1330 Win Hentschel Blvd.
West Lafayette, Indiana 47906

Re: K183348
Trade/Device Name: Reusable Silicone Cover CPRmeter 2
Regulation Number: 21 CFR 870.5210
Regulation Name: Cardiopulmonary resuscitation (CPR) aid
Regulatory Class: Class II
Product Code: LIX
Dated: November 30, 2018
Received: December 3, 2018

Dear Dan Dillon:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____K183348_____

Device Name: CPRmeter 2 CPR Feedback Device

Indications for Use:

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.

Prescription Use XX OR Over-the-Counter Use___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

Submitted By: Mari Kaada
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Device:

Trade Name:	CPRmeter 2 CPR Feedback Device
Common Name:	CPR Feedback Device Accessory
Classification Name:	Cardiopulmonary Resuscitation Aid

Indications for Use:

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.

Device Description:

The CPRmeter 2 is used as a guide in administering CPR to a suspected sudden cardiac arrest (SCA) victim at least 8 years old. The housing material of the CPRmeter 2 is composed of polycarbonate. It is small, lightweight, and powered by a replaceable battery. The device is approximately 153 mm × 64 mm × 25 mm (6.0″ × 2.5″ × 1.0″) and weighs approximately 191 g (6.7 oz) excluding batteries. The device is approximately the size and weight of a cell phone. It is intended to be placed between the responder's hands and the patient's chest during CPR. The CPRmeter 2 is intended for use by responders who have been trained in CPR and use of the CPRmeter 2. 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. It displays CPR feedback indicators for depth, rate, and release of chest compressions. It also counts the number of compressions in a series and provides notification of lack of expected CPR activity.

The Silicone Cover is an optional accessory to the CPRmeter 2 that is designed to cover the patient contacting side of the CPRmeter 2 and provide a larger patient-contact area during use. The Silicone Cover does not require a patient adhesive.

Comparison to Predicate Device:

The CPRmeter 2 with Silicone Cover is substantially equivalent to the CPRmeter 2. See Table 2-1. The addition of the Silicone Cover does not change the indications for use of the CPRmeter 2. The purpose of the Silicone Cover is to provide a larger patient contact area

during use. The materials, fundamental scientific technology, and principle of operation of the CPRmeter 2 are unchanged with the addition of the Silicone Cover. When the CPRmeter 2 is used without the Silicone Cover, a patient adhesive is required between the CPRmeter 2 and the patient's skin. When the CPRmeter 2 is used with the Silicone Cover, the patient adhesive is not required. Instead, the patient-contacting surface is soft silicone with a textured surface. The textured surface serves to stabilize the CPRmeter 2 on the patient's chest during use.

Table 2-1: Substantial Equivalence Comparison Table

	CPRmeter 2 with Silicone Cover (this 510(k))	**CPRmeter 2 (K173886)**
Indications for Use	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.	Identical
Prescription status	Prescription only	Identical
Design		
Measuring methods	Accelerometer and force sensor	Identical
Visual output	Light emitting diodes	Identical
Auditory output	None	Identical
Compression Feedback		
Depth	Visual	Identical
Rate	Visual	Identical
Release	Visual	Identical
Shelf Life	5 years	Identical
External Components		
Housing (top and bottom)	Basic structure of device, encasing all internal components.	Identical
Status LED	Indicates operating status of the device: • Green blinking light: Device in standby mode. • Orange steady light: Device has failed internal self-test and must be taken out of service. • No light: Battery needs replacement.	Identical
Display panel	Provides feedback to the user when performing chest compressions, approximately 30 mm × 37 mm.	Identical
Compression area	Provides area for the responder to perform compressions.	Identical
Placement guide	Indicates correct placement of the device on the patient's chest.	Identical

	CPRmeter 2 with Silicone Cover (this 510(k))	CPRmeter 2 (K173886)
On/Off button	Turns the device on or off. Device turns off automatically after 10 minutes of inactivity.	Identical
A hydrophobic membrane that prevents ingress of water and dust while equalizing atmospheric pressure changes within the device	Located on the side of the device	Identical
Rear cover screws	No rear cover or rear cover screws	Identical
Optional Silicone Cover		
Material	Silicone	Not Applicable
Dimensions (length × height × width)	156 mm × 31 mm × 67 mm	Not Applicable
Skin contacting surface	Silicone with an etched textured pattern	Not Applicable
Requires patient adhesive	No	Not Applicable
Shelf life	5 years	Not Applicable

Data Used in Determination of Substantial Equivalence

The following tests demonstrate that the Silicone Cover met applicable design and performance requirements and support a determination of substantial equivalence.

- Bench testing demonstrated acceptable performance of the device and adequate ability to withstand changes in ambient pressure, adequate physical fit, minimal water ingress, and other factors.
- Shelf life testing showed that the device could perform acceptably at the end of its labeled shelf life.
- Biocompatibility analysis was performed and demonstrated biocompatibility of the materials of the device.

Conclusion

Based on the results of the testing and other information submitted in the 510(k) application, the Silicone Cover does not raise any different questions regarding the safety or effectiveness of the CPRmeter 2. Further, the device was tested based on accepted scientific methods and the performance data demonstrate substantial equivalence; therefore, the CPRmeter 2 with Silicone Cover is considered to be substantially equivalent to the CPRmeter 2.