March 23, 2018

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

Re: K173886
Trade/Device Name: CPRmeter 2 CPR Feedback Device
Regulation Number: 21 CFR 870.5210
Regulation Name: Cardiopulmonary Resuscitation (CPR) Aid
Regulatory Class: Class II
Product Code: LIX
Dated: December 20, 2017
Received: December 21, 2017

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. 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.

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.

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,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173886

Device Name
CPRmeter™ 2 CPR Feedback Device

Indications for Use *(Describe)*
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.

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 K173886

CPRmeter™ 2 CPR Feedback Device
21 CFR 870.5210(b)
Date Prepared: March 22, 2018

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Device Information

Trade Name:	CPRmeter™ 2 CPR Feedback Device
Common/Usual Name:	CPR feedback device
Classification Name:	CPR aid with feedback
Regulation:	21 CFR 870.5210(b)
Product Code:	LIX
Device Class:	Class II
Classification Panel:	Cardiovascular

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.

Predicate Device:
The CPRmeter™ 2 CPR Feedback Device is substantially equivalent to the predicate device, the CPRmeter™ CPR Feedback Device (Laerdal Medical AS) as described in K151702, cleared on August 13, 2015.

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"× 2 ½"× 1") and weighs approximately 163 g (5.7 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 by means of a self-adhesive foam pad. The CPRmeter™ 2 is intended to be used by responders who have been trained in CPR and use of the CPRmeter™ 2. If the responder is in doubt about its appropriateness for use or the ability to use it, CPR is to be performed without using the CPRmeter™ 2 device.

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 CPRmeter™ 2 may be reused, provided proper cleaning procedures are performed after each patient use.

Substantial Equivalence:

The CPRmeter™ 2 is substantially equivalent to the predicate device, the CPRmeter™ CPR Feedback Device (510(k) No. K151702, cleared August 13, 2015). The table below presents the similarities and differences between the two products for substantial equivalence purposes. The differences between the subject device and the predicate do not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence and were developed using acceptable scientific methods for evaluation.

	CPRmeter™ 2 (subject of this submission)	**CPRmeter™ (K151702)**
Indications for Use	Used as a guide in administering cardiopulmonary resuscitation (CPR) to a suspected sudden cardiac arrest (SCA) victim at least 8 years old.	Identical
Housing Material	Polycarbonate	Polycarbonate/Siloxane
Measuring Methods	Accelerometer and force sensor	Identical
Depth Target	> 50 mm and < 60 mm	> 50 mm and < 70 mm
Rate Target	100-120 per minute	Identical
Release Target	Residual force ≤ 2.5 kg	Identical

Discussion of Tests and Test Results:

Design verification and validation testing demonstrates that the CPRmeter™ 2 device meets its functional requirements and supports a determination of substantial equivalence. In particular,

- Biocompatibility testing in accordance with FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process",* (June 16, 2016). Testing of the patient-contacting parts of the CPRmeter™ 2 demonstrates an appropriate biocompatibility profile for the device;
- Testing in accordance with AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance;* and AAMI/ANSI/IEC 60601-1-2:2007/(R)2012, *Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests* (Edition 3), demonstrates appropriate electrical safety and electromagnetic compatibility of the device;
- Nonclinical performance testing under simulated use conditions demonstrates acceptable performance of the device and adequate ability to withstand changes in ambient pressure, temperature and humidity, and other factors;
- Shelf life testing demonstrates that the device can perform acceptably at the end of its labeled shelf life; and
- Human factors testing validates that the device design and labeling are sufficient for effective use by the intended user.

Conclusions Drawn from the Tests:

The results of these tests support the conclusion that the CPRmeter™ 2 performs acceptably and does not raise any different questions regarding the safety or effectiveness compared to the predicate device, thus supporting a determination of substantial equivalence.