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

August 13, 2015

Laerdal Medical AS
% Dan Dillon
Regulatory Scientist
MED Institute
1330 Win Hentschel Boulevard, Ste 100
West Lafayette, Indiana 47906

Re: K151702
Trade/Device Name: CPRmeter CPR Feedback Device
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class III
Product Code: LIX
Dated: July 14, 2015
Received: July 16, 2015

Dear Mr. 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.

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 yours,

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): K151702

Device Name: CPRmeter™ CPR Feedback Device

Indications for Use:

The CPRmeter™ 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
Corporate Regulatory Affairs Manager
Laerdal Medical AS
Tanke Svilandsgate 30
P.O. Box 377
4002 Stavanger
Norway
(011) 47-51-51-16-30
Mari.Kaada@laerdal.no

Device:

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

Indications for Use:

The CPRmeter™ 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 Modified Cover is an optional accessory to the CPRmeter™ that is designed to cover the patient contacting side of the CPRmeter™ and provide a larger patient-contact area during use and does not require a patient adhesive. The CPRmeter™ is small, lightweight, and powered by a replaceable battery. The device is approximately 154 mm × 64 mm × 28 mm (6″ × 2½″ × 1″) and weighs approximately 227 grams (8 ounces) – 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™ is intended for use by responders who have been trained in CPR and use of the CPRmeter™. The CPRmeter™ is used as a guide in administering CPR to a suspected sudden cardiac arrest (SCA) victim at least 8 years old. When placed on the bare chest of a suspected SCA victim, the CPRmeter™ 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.

Comparison to Predicate Device:

The CPRmeter™ with the Modified Cover is substantially equivalent to the currently-marketed device (hereinafter referred to as the CPRmeter™ with the Predicate Cover). The Predicate Cover and the Modified Cover have the same intended use, which is to provide a larger patient contact area during use, and are similar in terms of design. Materials, fundamental scientific technology, and principle of operation are the same. When the CPRmeter™ is used with the

Predicate Cover, the patient adhesive is required to be placed between the CPRmeter™ and the patient's skin. When the CPRmeter™ is used with the Modified 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™ on the patient's chest during use.

Substantial Equivalence Comparison Table

	CPRmeter™ with Modified Cover (this 510(k))	**CPRmeter™ with Predicate Cover (K122050)**
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
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 25 mm × 25 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™ with Modified Cover (this 510(k))	**CPRmeter™ with Predicate Cover (K122050)**
On/Off button	Turns the device on or off. Device turns off automatically after 10 minutes of inactivity.	Identical
Rear cover	A hydrophobic membrane prevents ingress of water and dust while equalizing atmospheric pressure changes within CPRmeter™.	Identical.
Rear cover screws	Two (2) screws allow for opening the rear cover.	Identical
Optional Silicone Cover		
Prescription status	Prescription only	Identical
Device type	Optional accessory	Identical
Material	Silicone (Elastosil R 4000/70)	Identical
Length	157 mm	156 mm
Height	31 mm	24 mm
Width	66 mm	Identical
Skin contacting surface	Silicone with an etched textured pattern	Patient adhesive and silicone cover with smooth surface
Requires patient adhesive	No	Yes
Shelf life	5 years	Identical

Data Used in Determination of Substantial Equivalence

The following tests demonstrate that the Modified 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, temperature and humidity, 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 the biocompatibility of the material.

Conclusion

Based on the results of the testing and other information submitted in the 510(k) application, the Modified Cover does not raise any different questions regarding the safety or effectiveness compared to the Predicate Cover. Further, the device was tested based on accepted scientific

methods and the performance data demonstrate substantial equivalence; therefore, the CPRmeter™ with the Modified Cover is considered to be substantially equivalent to the CPRmeter™ with the Predicate Cover.