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

January 30, 2016

Resuscitation International, LLC
Hayden Fleming
Chairman and CEO
17797 N Perimeter Drive, Suite #105
Scottsdale, AZ 85255

Re: K153628
Trade/Device Name: ROSC-U Mini Chest Compressor (RMCC)
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class III
Product Code: DRM
Dated: December 18, 2015
Received: December 22, 2015

Dear Mr. Fleming:

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" (21CFR 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 Statement

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)*

K153628

Device Name

ROSC-U Mini Chest Compressor (RMCC)

Indications for Use *(Describe)*

To perform Cardiopulmonary Resuscitation (CPR) on adult patients and only adult patients in cases of clinical death as defined by a lack of spontaneous breathing and pulse.

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.

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510(k) Summary

510(k) Owner	Resuscitation International, LLC 17797 N Perimeter Drive, Suite #105 Scottsdale, AZ 85255 Phone: (949) 580.1266 Fax: (949) 580.1270
Contact person	Hayden Fleming Resuscitation International, LLC 17797 N Perimeter Drive, Suite #105 Scottsdale, AZ 85255 Phone: (949) 580.1266 Fax: (949) 580.1270 Email: hayden@resusintl.com
Submission date	December 18, 2015
Product Code:	
Common Name	Mechanical Cardiopulmonary Resuscitator
Trade Name	ROSC-U Mini Chest Compressor (RMCC)
Classification Name	compressor, cardiac, external
Regulation	870.5200
Class	Class III
Panel	General & Plastic Surgery
Product Code	DRM
Primary Predicate (MCC)	K102068 - Miniaturize Chest Compressor
Secondary Predicate	K090422 - LUCAS 2

Description

The RMCC is an automated, portable chest compressor, which provides continuous chest compressions as an adjunct to performing manual CPR. It is powered by a battery powered Control Unit. The RMCC provides consistent CPR support for cardiac arrest patients under conditions which might otherwise hinder the effectiveness of manual techniques.

The major components of the RMCC:

1. Compressor Assembly: contains a motor that drives the compressor pad to depress a patient's chest.
2. Control Unit: contains the battery, power ON/OFF switch, Function Control Panel and umbilical power cord connecting it to the compressor assembly. Note: The battery charger is a separate unit.
3. Torso Restraint: is placed underneath and around the back of the patient to firmly secure the compressor assembly to the patient.

Description (con't)

4. Stabilizer: serves a dual purpose; providing a head support and also attaches to the torso restraint to provide stability during continuous operation of the RMCC especially during patient transport.

Intended Use

The ROSC-U Mini Chest Compressor (RMCC) is intended for use as a Mechanical Cardiopulmonary Resuscitator for cardiac arrest patients under conditions which might otherwise hinder the effectiveness of manual techniques.

Indications for Use

To perform Cardiopulmonary Resuscitation (CPR) on adult patients and only adult patients in cases of clinical death as defined by a lack of spontaneous breathing and pulse.

Technological Characteristics

The predicate and the RMCC were compared in the following areas and found to have similar technological characteristics and to be equivalent:

	RMCC	MCC	LUCAS 2
User Population	Same	Same	Same
Compression Depth	Same	Same	Same
Compression Frequency	Same	Same	Same
Compression Duty Cycle	Same	Same	Same
Compression Modes	Same	Same	Same
Battery Voltage	Same		Same
Follows AHA Guidelines	Same	Same	Same
Intended Use	Same	Same	Same
Contraindications	Same	Same	Same
Torso Restraint	Same	Same	Same
Stabilizer	Same	Same	
Electromechanical Design	Same		Same

The predicate and the RMCC were compared in the following areas and found to have minor different technological characteristics. The following differences have been determined to not have any impact on the safety or efficacy of the RMCC.

	RMCC	MCC	LUCAS 2
Initial Battery Runtime	3.0 hours		45 minutes
Backplate	No Backplate		Backplate
Suction Cup	No Suction Cup		Suction Cup
Compressed Air Piston Design	Battery Powered	Compressed Air	
Electromechanical Design	Electrical	Pneumatic	

The following non-clinical performance tests were conducted:

Functional verification	PASS
IEC 60601-1 (2012): Medical Electrical Equipment – Part 1: General Requirements for Safety	PASS
IEC 60601-1-2 (2007): Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.	PASS

Conclusions from non-clinical performance data

After performing non-clinical performance studies, the data shows that the RMCC is substantially equivalent to the predicates as an external cardiac compressor.