November 9, 2021

Defibtech, LLC
Allison Bohren
Senior Regulatory Affairs Specialist
741 Boston Post Road
Guilford, Connecticut 06437

Re: K211289
Trade/Device Name: RMU-2000 Automated Chest Compression System
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class II
Product Code: DRM
Dated: October 14, 2021
Received: October 15, 2021

Dear Allison Bohren:

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,

Nicole Gillette
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211289

Device Name
RMU-2000 Automated Chest Compression System

Indications for Use *(Describe)*
The RMU-2000 Automated Chest Compression System (ACC) is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest defined as absence of spontaneous breathing and pulse, and loss of consciousness.

The RMU-2000 must only be used in cases where chest compressions are likely to help the patient.

The RMU-2000 ACC is intended for use as an adjunct to manual cardiopulmonary resuscitation (CPR) on adult patients when effective manual CPR is not possible (e.g., during patient transport, or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient personnel are available to provide effective CPR).

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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1. **Date Summary Prepared**

   April 26, 2021

2. **510(k) Owner Information**

   Defibtech, LLC
   741 Boston Post Road
   Guilford, CT 06437

3. **Primary Contact Information**

   Ms. Allison Bohren
   Senior Regulatory Affairs Specialist
   Defibtech, LLC
   741 Boston Post Road
   Guilford, CT 06437

   Phone: 203-453-6651, extension 159
   Fax: 203-453-6657
   Email: abohren@defibtech.com

4. **Trade (Proprietary) Name**

   RMU-2000 Automated Chest Compression System

5. **Common Name**

   Mechanical chest compressor

6. **Regulation/Classification Name and Code**

   External Cardiac Compressor (product code DRM)

7. **Regulation/Classification Code**

   21 CFR 870.5200

8. **Predicate Device Information**

The predicate device is the LUCAS Chest Compression System, which has been previously cleared in various 510(k) submissions. The RMU-2000 ACC is substantially equivalent in performance and safety to the LUCAS and accessories cleared under the following:

Proprietary Name	Manufacturer	Submission Number
LUCAS3.1 Chest Compression System	Jolife AB	#k173553

The submission utilized a reference device, RMU - 1000, which has been previously cleared in K141809.

9. Device Description

The RMU-2000 Automated Chest Compression (ACC) System is an automated, portable,

battery-powered device that provides chest compressions on adult patients who have cardiac arrest.

The RMU-2000 ACC, when applied to a patient who is unconscious and not breathing, is designed to:

- Provide consistent depth and rate chest compressions.
- Allow for automated chest compressions in both the in-hospital and out of hospital settings, including during patient transport.
- Be applied to the patient with minimal interruption of CPR.

The major components of the RMU-2000 ACC are the Backboard, the Frame and the Compression Module. The Backboard is placed under the patient to provide a base for the ACC system. After a single-use Suction Cup is pre-installed onto the Frame, the Compression Module is then mounted into the Frame, causing the Suction Cup to attach to the Compression Module's piston drive. The Compression Module and Frame assembly is then placed over the patient and snaps into the Backboard with self-locking latches. The Compression Module contains the user interface, a replaceable Battery Pack, and the piston drive and is used to generate the chest compressions.

The RMU-2000 ACC can be operated using a replaceable, rechargeable Battery Pack or with an external power adapter used in conjunction with the battery. A fully-charged, new Battery Pack can provide continuous operation for at least an hour and can be recharged in the Compression Module.

Once the RMU-2000 ACC has been powered on and applied to the patient, compressions are initiated by adjusting the piston to the patient's chest and pressing either of the Run Compressions buttons. Additional user interface features include a pause function, a warning indicator to notify the operator for possible misuse or malfunction, and a Battery Pack capacity gauge.

A Bluetooth® technology ON/OFF button on the user control panel allows the Compression Module to be wirelessly connected to a personal computer and for ACC data retrieval and event reporting when used in conjunction with utility software available at www.defibtech.com. A USB port on the underside of the Compression Module also allows connection to a personal computer when a wired connection is preferred or when a Bluetooth® connectivity is not possible or desired.

10. Indications for Use/Intended Use

The RMU-2000 Automated Chest Compression System (ACC) is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest defined as absence of spontaneous breathing and pulse, and loss of consciousness.

The RMU-2000 must only be used in cases where chest compressions are likely to help the patient.

The RMU-2000 ACC is intended for use as an adjunct to manual cardiopulmonary resuscitation (CPR) on adult patients when effective manual CPR is not possible (e.g., during patient transport, or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient personnel are available to provide effective CPR).

While the Indications for Use/Intended Use of the RMU-2000 contains minor clerical differences from the Indications for Use/Intended Use of the identified predicate device, the differences are not critical to the intended therapeutic use of the device, and the differences do not affect the safety and effectiveness of the device when used as labeled.

11. Comparison of Technology Characteristics

The intended use, operating principle, and basic design of the RMU-2000 ACC are the same as those in the LUCAS 3.1 predicate device. These similarities also include device features such as the compression mechanism, power sources, deployment operations and user interface controls. Both devices treat a similar adult patient population, with similar compressions rates, and have similar contraindication information. Both the Defibtech RMU-2000 and the LUCAS 3.1 utilize a suction cup which comes into direct contact with the patient's skin. The two devices are designed to meet the same resuscitation guideline recommendations, are marketed for the same clinical applications, and are intended to be used by similar populations of users in similar use environments.

In comparison, the technology differences between the RMU-2000 ACC and the predicate device includes an extended operational capability of 1 hour for the RMU-2000 compared to 45 minutes with the LUCAS 3.1. Additionally, there is a marginal difference in compression rates between the two devices (101±1 compressions per minute for the RMU-2000, and 102 ±1 compressions per minute for the LUCAS 3.1). Both device's compression rates are within the range for recommended American Heart Association (AHA) Guidelines compression rates. The available compression depth setting for the RMU-2000 (1.5 - 2.4 ±0.1 inch determined by anterior-posterior diameter of patient chest measured from piston position) is also different as compared to the LUCAS 3.1 (2.1 ± 0.1 inch for anterior posterior diameter ≥ 7.3 inch, 1.5 ± 0.1 inch for anterior posterior diameter < 7.3 inch for the LUCAS 3.1). As noted, the range of compression depth for the RMU-2000 is within the recommended range of AHA Guidelines compression depths.

The differences between the devices are not significantly clinically different and are related to design enhancements for users and implementation decisions.

12. Performance Testing

The RMU-2000 ACC uses the same underlying technologies to provide functionally equivalent performance characteristics as the predicate device. Additional testing, including hardware verification, software validation, design validation and compression waveform comparison, demonstrates that the RMU-2000 meets functional and performance specifications. Performance testing summaries, including waveform comparison testing, and applicable objective evidence are provided are as noted in Volume 018 of this submission. A summary of compliance testing and applicable objective evidence are provided in Volume 017 of this submission.

13. Conclusion Summary of Safety and Effectiveness

Testing and performance evaluations demonstrate that the RMU-2000 ACC is substantially equivalent to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness. The introduction of the RMU-2000 ACC does not present new issues of safety or effectiveness.