February 8, 2018

Jolife AB
% John Smith
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K173553
Trade/Device Name: LUCAS 3 Version 3.1 Chest Compression System
Regulation Number: 21 CFR 870.5200
Regulation Name: External cardiac compressor
Regulatory Class: Class II
Product Code: DRM
Dated: December 11, 2017
Received: December 11, 2017

Dear John Smith:

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K173553

Device Name

LUCAS 3 CHEST COMPRESSION SYSTEM version 3.1

Indications for Use *(Describe)*

LUCAS Chest Compression System 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.

LUCAS must only be used in cases where chest compressions are likely to help the patient.

The LUCAS device is intended for use as an adjunct to manual CPR 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 EMS 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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510(k) SUMMARY

Jolife's LUCAS 3 CHEST COMPRESSION SYSTEM version 3.1

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Date Prepared: February 6, 2018

Name of Device: LUCAS 3 CHEST COMPRESSION SYSTEM

Model: version 3.1

Common or Usual Name: External Cardiac Compressor

Classification Name: External Cardiac Compressor (21 CFR 870.5200)

Regulatory Class: Class II

Product Code: DRM

Predicate Devices

Jolife AB's LUCAS 3 CHEST COMPRESSION SYSTEM (K161768)

Michigan Instrument's Thumper Model 1005 (K851139)

Reference Devices

Jolife AB's LUCAS 2 CHEST COMPRESSION SYSTEM (K090422)

Intended Use/Indications for Use

LUCAS Chest Compression System 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.

LUCAS must only be used in cases where chest compressions are likely to help the patient.

The LUCAS device is intended for use as an adjunct to manual CPR 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 EMS personnel are available to provide effective CPR).

Device Description

The LUCAS Chest Compression System is a portable tool designed to overcome problems identified with manual chest compressions. The LUCAS device assists rescuers by delivering effective, consistent and continuous chest compressions as recommended in the American Heart Association guidelines and the European Resuscitation Council guidelines.

The LUCAS Chest Compression System can be used in a wide variety of situations and settings; on the scene, during patient movement, during transportation in road and air ambulances, in hospitals and catheterization laboratories.

The main parts of the LUCAS Chest Compression System include:

- A Back Plate which is positioned underneath the patient as a support for the external chest compressions.
- An Upper Part which contains the proprietary and rechargeable LUCAS Battery and the compression mechanism with the disposable Suction Cup.
- A Stabilization Strap which helps to secure the position of the device in relation to the patient.
- A Carrying Case.

In addition the following optional Accessories are offered as part of the system:

- LUCAS Battery, Dark Grey
- LUCAS Power Supply
- LUCAS Car Power Cable, 12-28VDC
- LUCAS PCI Back Plate
- LUCAS Battery Charger
- LUCAS Anti Slip, Slim Back Plate
- LUCAS Trolley

The LUCAS 3 version 3.1 is the same device as the cleared LUCAS 3 device (K161768) with exception of the option to change device factory default settings according to local protocols. LUCAS 3 version 3.1 in its factory default settings has identical performance characteristics as the predicate device LUCAS 3.

The LUCAS 3 version 3.1 factory default settings and setup options are consistent with 2015 American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines. Setup options should be changed only under the direction of a physician knowledgeable in cardiopulmonary resuscitation who is familiar with the literature in this area.

The compression rate and depth of the LUCAS 3 version 3.1 can be configured wirelessly using Bluetooth or WiFi to different fixed values. Other changeable settings include number of ventilation alerts, audible alert signal on/off, compression to ventilation ratio, ventilation pause duration, and automatic adjustment of the Pressure Pad. The new option to change device factory default settings is not available during treatment.

The device can also be configured to alter between different compression rates by pushing the ACTIVE (continuous or 30:2) key during ongoing compressions.

The LUCAS 3 version 3.1 captures device data for post event review in Physio-Control data management tools (LIFENET K102757 or internal service tool), which may be transmitted wirelessly using Bluetooth or WiFi (transmission is only available when device is powered OFF).

Summary of Technological Characteristics

The modified device LUCAS 3 version 3.1 has the same technological characteristics as the cleared predicate device LUCAS 3. Just as LUCAS 3, the LUCAS 3 version 3.1 delivers consistent and continuous chest compressions as recommended in the American Heart Association guidelines and the European Resuscitation Council guidelines.

Both devices share the identical principles of operations. The actuator of both devices is a suction cup which in turn is actuated by the nut of a ball screw drive. An electric motor drives the ball screw drive via a cog belt driven transmission.

The intelligence of the system is made up of four CPUs installed on four different subsystems i.e., the control system, the protective system, the charger system and the communication system. The protective and the charger systems share the same physical area of one PCB whereas the control system constitutes its own PCB.

The following technological differences exist between the subject and predicate devices:

- The LUCAS 3 version 3.1 software supports changing the device factory default settings by receiving data wirelessly using Bluetooth or WiFi.
- The LUCAS 3 version 3.1 setup options are similar to the options of the predicate device Thumper model 1005, but is limited to ranges that are consistent with 2015 American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines.
- The LUCAS 3 version 3.1 software provide the possibility to wirelessly transmit captured device data for post event review using Bluetooth or WiFi when the device is in Power OFF mode, whereas the predicate device LUCAS 3 only supports transmission by Bluetooth.

Wireless reception and transmission of data is only available when the device is in the powered OFF mode, not during treatment.

The communication system differs slightly as LUCAS 3 version 3.1 can use WiFi for both transmission and reception of data whereas the predicate device LUCAS 3 only transmits data using Bluetooth. Identical for both devices are that the communication system cannot be activated during device use.

The LUCAS 3 version 3.1 factory default settings and setup options are consistent with 2015 American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines. Setup options should be changed only under the direction of a physician knowledgeable in cardiopulmonary resuscitation who is familiar with the literature in this area.

Set up of the device is made by reception of configuration data from Physio-Control data management program using WiFi or Bluetooth. The device can only communicate with the external software when the device is in inactive mode (powered off). The device can only be set up in safe combinations of parameters as assessed in the Risk management file. The assessments are based on already available clinical data in combination with recommendations by the American Heart Association (AHA).

The described modifications substantially follow the established guidelines for CPR and have hence not raised any different questions regarding safety or effectiveness.

Purpose of 510(k)

The purpose of this 510(k) is to modify the LUCAS 3 Chest Compression System by introducing the option to change device factory default settings according to local protocols such as compression rate and depth, number of ventilation alerts, audible alert signal on/off, compression to ventilation ratio, ventilation pause duration, and automatic adjustment of the Pressure Pad. The device can also be configured to alter between compression rates by pushing the ACTIVE (continuous or 30:2) key during ongoing compressions.

Performance Data

Device Set up is controlled by software. The LUCAS 3 version 3.1 software is a modification of the software for the predicate device LUCAS 3 (K161768). The LUCAS 3 software has been developed based on the methods of IEC 62304: 2006 + A1:2015, the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Device, Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software and Guidance for Off-the-Shelf Software use in Medical Devices. In addition the FDA guidance documents addressing Content of Premarket Submissions for Management of Cybersecurity in Medical Devices and Post market Management of Cybersecurity in Medical Devices have been used during the software development process.

Verification and validation testing have been performed for LUCAS 3 version 3.1 with approved result. Nonclinical performance testing under simulated physiological conditions has been performed demonstrating the reliability of delivering specific compression depth and rate over the intended duration of use. Additional verification and validation activities are recorded in system and, where appropriate, unit test reports.

In all instances, the LUCAS 3 version 3.1 functioned as intended and results observed were as expected.

The device can only be set up in safe combinations of parameters as assessed in the Risk management file. The assessments are based on already available clinical data in combination with recommendations by the American Heart Association (AHA). No new clinical testing has been performed for this version. LUCAS 3 version 3.1 has a safety and effectiveness profile that is similar to the predicate devices.

Conclusions

The LUCAS 3 version 3.1 has the same intended use and indications, technological characteristics and principles of operation and is as safe and effective as the predicate device LUCAS 3. The LUCAS 3 version 3.1 also has similar technological characteristics with set-able compression parameters as its predicate device Thumper Model 1005.

In addition, the minor technological differences between the LUCAS 3 version 3.1 and its predicate devices raise no new issues of safety or effectiveness.

Performance data demonstrate that the LUCAS 3 version 3.1 is as safe and effective as the predicate devices. Thus, the LUCAS 3 version 3.1 is substantially equivalent.