July 29, 2022

AdvancedCPR Solutions LLC
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K221901
Trade/Device Name: EleGARD
Regulation Number: 21 CFR 880.6080
Regulation Name: Cardiopulmonary Resuscitation Board
Regulatory Class: Class I
Product Code: FOA
Dated: June 28, 2022
Received: June 30, 2022

Dear Paul Dryden:

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,

David Wolloscheck, Ph.D.
For Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K221901

Device Name

EleGARD™ Patient Positioning System

Indications for Use *(Describe)*

The EleGARD™ Patient Positioning System (EleGARD) is a cardiopulmonary board which may elevate a patient's head and thorax: including during airway management; during manual CPR, manual CPR adjuncts, CPR with the LUCAS® Chest Compression System or ARM XR Automated Chest Compressor; and patient transport. EleGARD is indicated for adults only when used with the LUCAS Chest Compression System or the ARM XR Automated Chest Compressor. When not used with an automated compression system, EleGARD can be used for adults and children, not including infants and neonates.

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

Date Prepared: 28-Jul-22

AdvancedCPR Solutions LLC
5201 Eden Ave., Suite 300
Edina, MN 55436
Tel – 763.259.3722

Official Contact: Philip Faris - CEO

Proprietary or Trade Name: EleGARD™ Patient Positioning System

Common/Usual Name: Cardiopulmonary board

Classification Name: FOA - Cardiopulmonary resuscitation board (21 CFR 880.6080)

Predicate Device: K191689 – AdvancedCPR Solutions LLC

Reference Device K211289 – Defibtech RMU 2000

Device Description:
The EleGARD™ patient positioning system is an electrically powered device on which a patient is placed. It can be used to elevate a patient's head and thorax during a number of different procedures, e.g., airway management and different CPR techniques.

The EleGARD™ acts as a back board for airway management and for performing CPR. It allows the user to position the patient in supine or with the head and thorax elevated. The EleGARD™ is a cardiopulmonary back board which is placed under the patient.

There are several different CPR methods which use a back board, stretcher or bed, e.g., manual CPR, manual CPR Adjuncts, and with the Defibtech Chest Compression System and ARM XR backplate or with the LUCAS Chest Compression System as previously cleared under K191689.

Indications for Use:
The EleGARD™ Patient Positioning System (EleGARD) is a cardiopulmonary board which may elevate a patient's head and thorax: including during airway management; during manual CPR, manual CPR adjuncts, CPR with the LUCAS® Chest Compression System or ARM XR Automated Chest Compressor; and patient transport. EleGARD is indicated for adults only when used with the LUCAS Chest Compression System or the ARM XR Automated Chest Compressor. When not used with an automated compression system, EleGARD can be used for adults and children, not including infants and neonates.

Patient Population:
Patients who may benefit from elevation of the head and neck, including those patients in need of airway management, elevation of the head, and those undergoing CPR. Specifically, when used with the automated compression systems the population is limited to adults and when not used with an automated compression system, EleGARD can be used for adults and children, not including infants and neonates.

Contraindications:
It is recommended that EleGARD™ no be used under the following conditions:

- When it is not possible to position the patient safely or correctly on the EleGARD
- If the patient weighs more than 350 pounds

Environments of Use:
Hospital and pre-hospital

510(k) Summary

Table 1 - Table of the Similarities and Differences of Predicate vs. Proposed Device

	Proposed **EleGARD™ Patient Positioning System with Defibtech ARM XR backplate**	**Predicate** **EleGARD™ Patient Positioning Systems with LUCAS backplate** **K191689**	**Comments**
Procode / Classification / CFR	FOA – cardiopulmonary board CFR 880.6080	FOA – cardiopulmonary board CFR 880.6080	Similar
Indications for Use	The EleGARD™ Patient Positioning System (EleGARD) is a cardiopulmonary board which may elevate a patient's head and thorax: including during airway management; during manual CPR, manual CPR adjuncts, CPR with the LUCAS® Chest Compression System or ARM XR Automated Chest Compressor; and patient transport. EleGARD is indicated for adults only when used with the LUCAS Chest Compression System or the ARM XR Automated Chest Compressor. When not used with an automated compression system, EleGARD can be used for adults and children, not including infants and neonates.	The EleGARD™ Patient Positioning System is cardiopulmonary board which may elevate a patient's head and thorax including during airway management; during manual CPR, manual CPR adjuncts, CPR with the LUCAS Chest Compression Systems; and patient transport	Similar
Prescriptive	Trained medical personnel	Trained medical personnel	Similar
Environments of use	Hospital and pre-hospital	Hospital and pre-hospital	Similar
Technology	Method to elevate the head and torso via manual and electro-mechanical lifting and hold in place	Method to elevate the head and torso via manual and electro-mechanical lifting and hold in place	Similar
Used with Automatic Compression / Decompression Systems	Yes, adding Dibetech ARM XR®	Yes with LUCAS	Similar, but different Automatic Compression / Decompression Systems
Performance	From K191689 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-12 Cleaning	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-12 Cleaning	Similar
Contraindications	It is recommended that EleGARD™ not be used under the following conditions: • When it is not possible to position the patient safely or correctly on the EleGARD • If the patient weighs more than 350 pounds	It is recommended that EleGARD™ not be used under the following conditions: • When it is not possible to position the patient safely or correctly on the EleGARD • If the patient weighs more than 350 pounds	Similar

510(k) Summary

Substantial Equivalence Rationale and Discussion of Differences

The EleGARD™ is viewed as substantially equivalent to the predicate device because:

Indications –
The EleGARD™ is designed to elevate a patient's head and thorax during airway management, various modalities of CPR and patient transport.
Discussion – The indications for use are similar to the predicate K191689 and within the intended use of the accessory backplate of the reference K211289. The patient population was clarified in the indications for to be consistent with and without use of automatic compression systems. There were no differences between the predicate and subject device.

Environment of Use –
All devices have the same environments of use: hospital and pre-hospital to be used by trained medical personnel
Discussion – The environments of use and personnel are similar to the predicate device.

Technology –
The technology is to stabilize the body position and to elevate the patient's head and thorax during CPR. The positioning of the head and thorax is similar to the predicate. The only modification is the option of using the Defibtech ARM XR backplate, K211289, for the LUCAS backplate to connect to the applicable device.
Discussion – There is no change in technology between the proposed device and the predicate and the option of the Defibtech ARM XR backplate is similar to that of the LUCAS backplate. There are no technological differences in the backplates and their use with the EleGARD™ that would raise different risk concerns.

Non-clinical Testing Summary
Biocompatibility of Materials –
There are no direct patient contacting materials of the EleGARD™.
Discussion – The sponsor offers 2 different coverings, one is identical to K191689 and the other has supportive ISO 10993-1 testing.

Electrical, EMC, EMI testing –
Testing was performed for K191689. The modification has not effect on this performance. K191689 included testing per ANSI/AAMI/ES 60601-1 and IEC 60601-1-2, and the device performed as intended and met the requirements.

Bench testing –
Testing and verification was performed to evaluate the ability to connect the Defibtech ARM XR backplate with the EleGARD™. This testing included Patient Position, connection to Optional Associate Equipment, Carrying, a review of any different Risk Mitigation, there were none, and the ability to fit within the EleGARD™ and that the placement of the Defibtech ARM XR backplate can be attached to the main ARM XR unit.
Discussion – Upon completion of the tests, it was found to meet its performance requirements.

Substantial Equivalence Conclusion –
The proposed addition of the Defibtech ARM XR backplate does not raise different questions of safety compared to the predicate and thus can be found substantially equivalent.