February 13, 2020

Minnesota Resuscitation Solutions, d.b.d AdvancedCPR Solutions
c/o Paul Dryden
Manager
ProMedic LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K191689
Trade/Device Name: EleGARD Patient Positioning System
Regulation Number: 21 CFR 880.6080
Regulation Name: Cardiopulmonary Resuscitation Board
Regulatory Class: Class I, reserved
Product Code: FOA,
Dated: January 14, 2020
Received: January 15, 2020

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,

for Geeta Pamidimukkala
Acting 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: 06/30/2020
*See PRA Statement on last page.*

510(k) Number *(if known)*

K191689

Device Name

EleGARD™ Patient Positioning System

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ XX 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
K191689

**Date Prepared:** 13-Feb-2020

## I Submitter

Minnesota Resuscitation Solutions, d.b.d AdvancedCPR Solutions
5201 Eden Ave., Suite 300
Edina, MN 55436
Tel – 763.259.3722

Submitter Contact: Philip Tetzlaff, CTO

Submission Correspondent: Paul Dryden, ProMedic, LLC

## II Device

Proprietary or Trade Name**:** EleGARD™ Patient Positioning System

Common/Usual Name: Cardiopulmonary resuscitation board
Classification Name: Cardiopulmonary resuscitation board (21CFR 880.6080)
Regulatory Class: I
Product Code: FOA

## III Predicate Device

Minnesota Resuscitation (now AdvancedCPR Solutions)
Heads Up Platform - Class I exempt, FOA, 21CFR 880.6080

## IV 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.

It may be used with the patient lying flat or may elevate the patient's thorax and head.
The device would be used in emergency conditions when healthcare professionals need to: provide airway management, perform CPR with manual / hand compressions, adjunctive manual CPR devices, and a LUCAS mechanical compression device, perform manual bag / mask ventilation, and transport a patient.

## V Indications for Use

The EleGARD™ Patient Positioning System 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 Systems; and patient transport.

**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.

**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

**Environments of Use:**
Hospital and pre-hospital

## VII Comparison of Technological Characteristics and Performance with the Predicate

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

| | **Proposed EleGARD™ Patient Positioning** | **Predicate Head Up Platform** |
|---|---|---|
| **Procode** | FOA – cardiopulmonary resuscitation board<br>CFR 880.6080 | FOA – cardiopulmonary resuscitation board<br>CFR 880.6080 |
| **Indications for Use** | 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 | Intended to assist in elevating the head and shoulders of a patient from a supine position to approximately 30 degrees and may be used during various procedures, i.e., airway management procedures, CPR, etc. |
| **Prescriptive** | Trained medical personnel | Trained medical personnel |
| **Environments of use** | Hospital and pre-hospital | Hospital and pre-hospital |
| **Technology** | Method to elevate the head and torso via manual and electro-mechanical lifting and hold in place | Manual mechanical means to elevate the head and torso and hold in place |
| **Performance** | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-12<br>Cleaning of patient contacting surfaces<br>Compatibility of Lucas backplate connection | Device was not electrical |
| **Contraindications** | It is recommended that EleGARD™ not be used under the following conditions:<br>• When it is not possible to position the patient safely or correctly on the EleGARD<br>• If the patient weighs more than 350 pounds | It is recommended that EleGARD™ not be used under the following conditions:<br>• When it is not possible to position the patient safely or correctly on the EleGARD<br>• If the patient weighs more than 350 pounds |
| **Patient contacting materials** | Evaluated via ISO 10993-1 | Evaluated via ISO 10993-1 |

**Substantial Equivalence Rationale**

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

**Indications –**

- Both the EleGARD™ and predicate device are designed to elevate a patient's head and thorax during airway management, various modalities of CPR and patient transport. The differences in the indications is that the subject device can be used with the LUCAS chest compression system. Performance testing was completed to support this change in indication.

**Environment of Use –**

- All devices have the same environments of use: hospital and pre-hospital to be used by trained medical personnel

**Technology** –

- The technology is to stabilize the body position and to elevate the patient's head and thorax during CPR. The positions of the head and thorax are similar but the means to elevate is different between the proposed EleGARD™ and the predicate Head Up Platform.
- The difference is electro-mechanical elevations vs. manual elevation. The practical nature of having electro-mechanical assistance in place of manual mechanical spring strut to elevate the patient when needed has been evaluated and does not raise any new concerns for safety or effectiveness that are not typical of other electro-mechanical devices.

## VIII Performance Data

**Biocompatibility of Materials –**
The patient contacting materials of the EleGARD™ have been evaluated according to ISO 10993-1. Testing included by Cytotoxicity, Sensitization and Irritation.

**Electrical, EMC, EMI testing –**
We have evaluated the proposed device per ANSI/AAMI/ES 60601-1, IEC 60601-1-2, and IEC 60601-1-12.
The proposed device met the requirements of the standards.

**Bench testing –**
The proposed device was tested for functional performance of raising and lowering the device to the specified positions; Electrical safety ( ES160601-1); EMC (IEC60601-1-2); and Safety for use in EMS environments (IEC 60601-1-12), software verification and system verification (*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices)* and compatibility of the backplate connection.

## IX Conclusion

The sponsor has demonstrated through performance testing, design and features to be substantially equivalent to the predicate device.