SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Automated External Defibrillator
Device Trade Name:	LIFEPAK® CR2 Defibrillator
Device Product Code:	MKJ
Applicant's Name and Address:	Physio-Control, Inc. 11811 Willows Road NE Redmond, WA 98052 USA
Date(s) of Panel Recommendation:	N/A
Premarketing Approval Application (PMA) Number:	P170018
Date of FDA Notice of Approval:	December 21, 2018

II. INDICATIONS FOR USE

The LIFEPAK® CR2 Defibrillator is indicated for use on patients 1 year of age and older in cardiopulmonary arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement).

The cprCOACH™ Feedback Technology in the LIFEPAK CR2 defibrillator is indicated for use on cardiopulmonary arrest patients and provides CPR guidance in accordance with the AHA Guidelines for patients 1 year of age and older.

The LIFEPAK® CR2 Defibrillator is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support/AED, advanced life support, or a physician-authorized emergency medical response training program.

The LIFEPAK® CR2 Defibrillator is indicated to be used with the QUIK-STEP Pacing/ECG Defibrillation Electrodes and the LIFEPAK CR2 Lithium Battery.

III. CONTRAINDICATIONS

The LIFEPAK® CR2 Defibrillator is not indicated for patients who are conscious or responsive.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the LIFEPAK CR2 labeling.

V. DEVICE DESCRIPTION

The LIFEPAK CR2 Defibrillator is a small, lightweight, battery powered automated external defibrillator (AED) intended for use by minimally trained responders to treat

victims of sudden cardiac arrest. The LIFEPAK CR2 Defibrillator incorporates an easy to use interface for the responder to activate the device, apply the defibrillation electrodes, deliver a shock (semi-automatic model) or the device will automatically deliver a shock (automatic model), and perform CPR. Using voice prompts, graphics, audible tones and buttons, the responder is guided through device use.

Major accessories used with the LIFEPAK CR2 Defibrillator are the following:

- The LIFEPAK CR2 Defibrillator is shipped with disposable, single use QUIK-STEP Pacing/ECG Defibrillation Electrodes, which are pre-connected electrodes that can be used to treat both adults and children.

- The LIFEPAK CR2 Defibrillator is powered by a non-rechargeable lithium manganese dioxide battery with a typical capacity of 166 shocks at 200 joules or 800 minutes of operation when powered on.

- ***Principle of Operation:***

  Sudden cardiac arrest is usually caused by a malfunction in the heart's electrical system, called ventricular fibrillation (VF). This critical condition prevents the heart from pumping blood throughout the body. VF can cause death within seconds.

  Defibrillation is a relatively simple procedure that involves placing defibrillation electrodes on a victim's exposed chest and delivering an electrical shock to the heart. The externally-delivered shock often restores the heart's electrical system to a normal rhythm. Combined with cardiopulmonary resuscitation (CPR), defibrillation provides the most effective care for victims in cardiac arrest.

  In the LIFEPAK CR2 there are two (2) systems which are used for electrocardiogram (ECG) analysis. These systems recommend whether or not a patient should be given a defibrillation shock. These systems make it possible for individuals not trained to interpret ECG rhythms to provide potentially-lifesaving therapy to victims of ventricular fibrillation or pulseless ventricular tachycardia (VT).

  - ***Shock Advisory System™ (SAS)*:** The SAS algorithm is the same algorithm used in other PMA approved LIFEPAK defibrillators (P160012 and P160026). SAS is used to analyze the ECG rhythm during the first rhythm analysis after the defibrillation electrodes have been placed on the patient when CPR is not being performed. It is also used during subsequent rhythm analyses when the user has been instructed to stop CPR.

  - ***cprINSIGHT™ Analysis Technology*:** The cprINSIGHT Analysis Technology is an additional analysis system that enables the defibrillator to analyze the patient's heart rhythm while CPR is being performed. This reduces pauses in chest compressions which are normally required for rhythm analysis and thus the ongoing CPR helps maintain circulation of the blood. When the ECG rhythm is determined to be nonshockable, the pause for analysis can be eliminated altogether, allowing for continuous CPR. When the rhythm is determined to be shockable, the necessary pause time in chest compressions is shortened to the

time needed for the rescuer to stand clear and deliver the shock. The cprINSIGHT Analysis Technology can be set to be on or off. As noted previously, the LIFEPAK CR2 Defibrillator always uses the SAS algorithm for the first rhythm analysis in each patient.

Further descriptive detail regarding the Shock Advisory System and cprINSIGHT Analysis Technology can be found within the LIFEPAK CR2 Defibrillator Operating Instructions.

- ***Device Features*:** A summary of the main features of the LIFEPAK CR2 Defibrillator are listed below. Details regarding each of these features can be found in the LIFEPAK CR2 Defibrillator Operating Instructions (labeling).

  - Readiness for use indicator flashes every 6 seconds to indicate device status
  - Pre-connected QUIK-STEP electrode tray
  - cprCOACH Feedback Technology/compression detection provides CPR coaching (feedback) to user regarding compressions, when appropriate
  - ClearVoice Technology - for delivery of voice prompts to the device user
  - cprINSIGHT™ Analysis Technology
  - Child Mode delivers lower energy levels that are appropriate for young children
  - Dual Language capability
  - Semiautomatic and fully automatic device models
  - Biphasic truncated exponential (BTE) defibrillation waveform
  - Shock Advisory System (SAS)
  - Multiple configurable defibrillation shock energy levels from 150 to 360 joules for adult mode operation
  - Multiple configurable defibrillation shock energy levels from 35 to 90 joules for child mode operation
  - Simple User Interface
  - Automatic Self-Tests - to assess device readiness for use
  - Data Management - for capture of ECG/event data
  - Wireless data transmission

  For visual reference, diagrams of the LIFEPAK CR2 defibrillator are provided below in Figure 1 (exterior views) and Figure 2 (interior views). Additional diagrams and pictures of the device can be found in the LIFEPAK CR2 Operating Instructions.

- ***Device User Interface*:** The LIFEPAK CR2 is designed for public access ease of use by reducing the number of steps traditionally required for defibrillation. As such, the device has a simple user interface. For example: The LIFEPAK CR2 is shipped ready to use with preprogrammed biphasic escalating energy and operating settings. The defibrillator includes an integral lid that protects the electrodes and the same button that opens the lid, turns the device power on (see Figure 1). The defibrillator voice prompts and audible tones guide the device user, including when to apply electrodes, and provides instructions for standing clear or pressing the flashing shock

button, depending upon the version of the device being used (fully automatic or semiautomatic).

- ***Device Versions*:** The LIFEPAK CR2 is offered in two (2) models: fully automatic or semiautomatic.

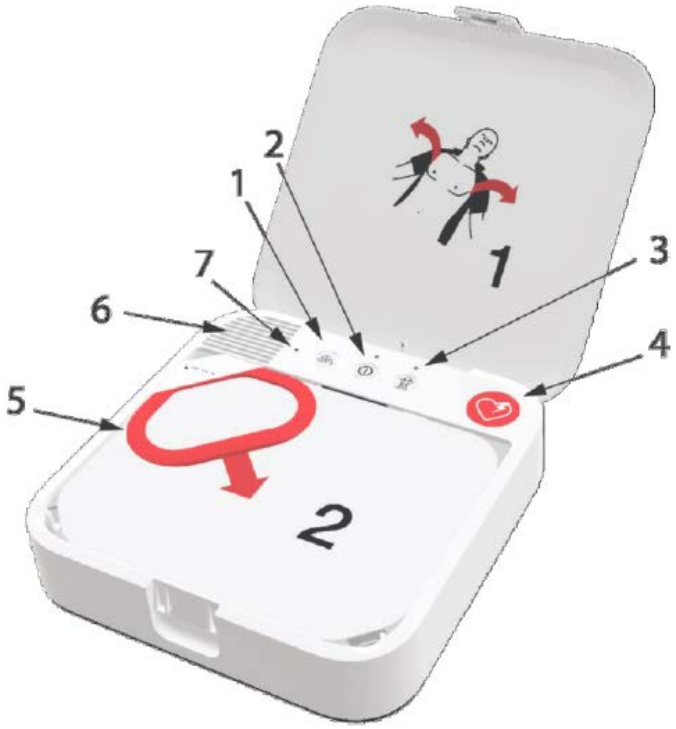
  - ***Fully automatic AED*:** The fully automatic model of the LIFEPAK CR2 only requires the responder to assess the patient, open the defibrillator, apply the electrodes to the victim's chest and follow the voice prompts. The defibrillator will automatically analyze the victim's heart rhythm, charge, and if a shockable rhythm is detected, the defibrillator will alert the responder that a defibrillation pulse (shock) will be delivered and to stand clear of the patient, and then deliver the shock without any responder assistance. The defibrillator delivers shocks through the defibrillation electrodes on the victim's chest.

  - ***Semiautomatic AED*:** The semiautomatic model of the LIFEPAK CR2 evaluates the heart rhythm and if a shockable rhythm is detected, the voice prompt instructs the responder to press the flashing "shock" button on the defibrillator to deliver the shock through the defibrillation electrodes on the victim's chest.

Figure 1: LIFEPAK CR2 defibrillator – top and bottom exterior views

Items in Figure 1	*Feature*	*Description*
1	Readiness indicator	The green LED flashes every 6 seconds if the defibrillator is ready for use. The indicator is steady on if the defibrillator is turned on, and steady off if the defibrillator needs attention.
2	Latch	To open the defibrillator, insert a finger in the recessed area and pull up.
3	USB port	The USB connection is used to connect the defibrillator to a computer, to establish communication with LIFELINK™ Central AED Program Manager or LIFENET® System.
4	Battery compartment	Insert the LIFEPAK CR2 lithium battery into the battery compartment until it clicks into place.
5	Warning symbol	See General Dangers and Warnings in the LIFEPAK CR2 Operating Instructions.

Figure 2: LIFEPAK CR2 defibrillator – interior view



Item in Figure 2	*Feature*	*Description*
1	Language button	If the defibrillator has two (2) languages installed, press the LANGUAGE button to switch between languages.
2	On/Off button	The defibrillator turns on automatically when the lid is opened. Press and hold the ON/OFF button for 3 seconds to turn the defibrillator off. Press again to turn the defibrillator back on. The green LED is illuminated when the defibrillator is on.
3	Child Mode button	Press the CHILD MODE button to switch between Adult mode and Child mode. When Child mode is selected, the green LED above the CHILD MODE button is illuminated and a voice prompt announces "Child mode."
4	Shock button/ indicator	On fully automatic defibrillators, the SHOCK indicator flashes when the defibrillator is preparing to deliver a shock. On semiautomatic defibrillators, press the flashing SHOCK button to deliver a shock to the patient.
5	Red handle	During a cardiac arrest event, the red handle is pulled to reveal the electrodes.
6	Speaker	Provides audio voice prompts and tones.
7	Noise sensor	The noise sensor monitors the noise level of the surrounding area while the defibrillator is in use.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Defibrillation is the only currently available treatment for termination of VF or pulseless VT. Public access defibrillation is designed to provide potentially lifesaving treatment prior to the arrival of emergency personnel.

VII. MARKETING HISTORY

The LIFEPAK CR2, QUIK-STEP Pacing/ECG Defibrillation Electrodes, and the LIFEPAK CR2 Lithium Battery are new products and have not been marketed in the US.

The LIFEPAK CR2 and the accessories have been in commercial distribution in non-US countries since October 2016. As of October 2018, the LIFEPAK CR2 is in commercial distribution in the following 33 non-US countries:

- Albania
- Australia
- Austria
- Bahrain
- Canada
- Denmark
- Finland
- France
- Germany
- Hungary
- Iran
- Ireland
- Israel
- Italy
- Japan
- Kuwait
- Liechtenstein
- Luxembourg
- Malaysia
- Malta
- Netherlands
- New Zealand
- Norway
- Panama
- Peru
- Poland
- Singapore
- Spain
- Sweden
- Switzerland
- Turkey
- United Arab Emirates
- UK

The LIFEPAK CR2 and the accessories have not been withdrawn from the market in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the LIFEPAK CR2.

- Failure to identify shockable arrhythmia;
- Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury;
- Inappropriate energy delivery which could cause failed defibrillation or post-shock dysfunction;
- Myocardial damage;
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents;
- Electromagnetic interference (EMI) from the defibrillator impacting other devices especially during charge and energy transfers;
- Incorrectly shocking a pulse sustaining rhythm and inducing VF or cardiac arrest;
- Bystander shock from patient contact during defibrillation shock;

- Interaction with pacemakers;
- Skin burns around the electrode placement area;
- Allergic dermatitis due to sensitivity to materials used in electrode construction; and
- Minor skin rash.

IX. SUMMARY OF PRECLINICAL STUDIES

The LIFEPAK CR2 underwent bench and animal testing as well as software verification and validation appropriate for major level of concern devices. This non-clinical information included:

A. Bench Testing

Table 1 summarizes the major bench testing conducted to demonstrate performance of the LIFEPAK CR2, including conformance with applicable performance standards.

Table 1. Major Bench Testing

Test Title	Results
Electrical Safety (IEC 60601-1:2005 Edition 3 and IEC 60601-2-4:2010 Edition 3)	Pass
Electromagnetic Compatibility (IEC 60601-1-2:2014 Edition 4) with Home Use environment requirements	Pass
Software Verification/Validation	Pass
Environmental Testing	Pass
Shock Advisory System Performance Testing	Pass
cprINSIGHT Analysis Technology Performance Testing	Pass
Motion Detection Testing	Pass
System Design Verification	Pass
Hardware Design Verification	Pass
Functional Testing	Pass
Battery Testing	Pass
Energy Accuracy and Waveform Testing	Pass
Time to Shock Ready Testing	Pass
Mechanical (Vibration, Drop, etc.) Testing	Pass
Cleaning Tests	Pass
Packaging Tests	Pass

B. Shelf Life Testing

Shelf life testing was conducted to demonstrate a 4-year shelf life for the QUIK-STEP Electrodes and 4-year standby life for the Lithium manganese dioxide battery used with the LIFEPAK CR2.

C. Software

The software for the LIFEPAK CR2 was verified/validated and documented as a Major Level of Concern device according to the FDA guidance document "Guidance

for the Content of Premarket Submissions for Software Contained in Medical Devices." The documentation included level of concern, software description, device hazard analysis, software requirements specification, software architecture diagrams, software design specifications, requirements traceability matrix, software development environment description, verification and validation documentation, revision level history, report of unresolved anomalies, discussion of tools to detect run-time errors, and cybersecurity documentation. Unit, integration, and system-level testing was documented and demonstrated that the software for the LIFEPAK CR2 performs as intended.

D. Defibrillation Waveform

The LIFEPAK CR2 delivers a Biphasic Truncated Exponential waveform, with voltage and duration compensation for patient impedance.

- ***Shock Advisory Algorithms***

The results of performance testing of the SAS algorithm and the cprINSIGHT algorithm are shown in Tables 2-5. This data has been reported per the American Heart Association (AHA) Scientific Statement: "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," Circulation 1997; 95:1677-1682.[1]

Table 2. AHA Recommendations and SAS Performance for Adult Patients

Rhythm Category	Sample Size (AHA Recommended)	Sample Size (Tested)	Performance Goal (AHA Recommended)	Test Result	One-Sided 90% Lower Confidence Limit
	Shockable				
Coarse VF	200	206	>90% sensitivity	99.0% sensitivity	97.4%
Rapid VT, pulseless	50	65	>75% sensitivity	84.6% sensitivity	77.3%
	Nonshockable				
NSR	100	509	>99% specificity	100.0% specificity	99.5%
Other QRS	30	749	>95% specificity	98.9% specificity	98.3%
Asystole	100	124	>95% specificity	100.0% specificity	98.2%
	Intermediate				
Fine VF	25	32	Report only	53.1% shocked	40.4%
Other VT	25	27	Report only	29.6% shocked	18.1%

Table 3. AHA Recommendations and SAS Performance for Pediatric Patients

Rhythm Category	Sample Size (Tested)	Performance Goal (AHA Recommended)	Test Result	One-Sided 90% Lower Confidence Limit
Shockable				
Coarse VF	63	>90% sensitivity	98.4% sensitivity	94.0%
Nonshockable				
NSR	69	>99% specificity	100.0% specificity	96.7%
Other QRS	507	>95% specificity	100.0% specificity	99.5%
Asystole	60	>95% specificity	100.0% specificity	96.2%
Intermediate				
Fine VF	1	Report only	100.0% shocked	10.0%

Table 4. AHA Recommendations and cprINSIGHT Analysis Performance for Adult Patients, results of testing on rhythm segments during CPR periods

Rhythm category	Sample Size	Decided Without a Pause	Performance Goal (AHA Recommended)	Test Result	One-sided 90% Lower Confidence Limit
Shockable					
Coarse VF	1282	80.6%	>90% sensitivity	96.4% sensitivity	95.6%
Rapid VT, pulseless	52	61.5%	>75% sensitivity	65.6% sensitivity	52.8%
Nonshockable					
NSR	72	93.1%	>99% specificity	100.0% specificity	96.6%
Other QRS	2527	79.3%	>95% specificity	97.8% specificity	97.3%
Asystole	1790	59.9%	>95% specificity	97.0% specificity	96.2%
Intermediate					
Fine VF	113	39.8%	Report only	48.9% shocked	
Other VT	49	67.3%	Report only	33.3% shocked	

Table 5. AHA Recommendations and cprINSIGHT Analysis Performance for Pediatric Patients, results of testing on rhythm segments during CPR periods

Rhythm category	Sample Size	Decided Without a Pause	Performance Goal (AHA Recommended)	Test Result	One-sided 90% Lower Confidence Limit
Shockable					
Coarse VF	38	84.2%	>90% sensitivity	100.0% sensitivity	93.1%
Rapid VT, pulseless	0	--	--	--	--
Nonshockable					
NSR	13	100%	>99% specificity	100.0% specificity	83.8%

Rhythm category	Sample Size	Decided Without a Pause	Performance Goal (AHA Recommended)	Test Result	One-sided 90% Lower Confidence Limit
Other QRS	472	72.0%	>95% specificity	99.7% specificity	98.9%
Asystole	176	72.2%	>95% specificity	97.6% specificity	94.8%
Intermediate					
Fine VF	0	--	--	--	--
Other VT	1	100%	Report only	0 shocked	

- ***Animal Study***

An experimental study by C. Killingsworth titled "Defibrillation threshold and cardiac responses using an external biphasic defibrillator with pediatric and adult adhesive patches in pediatric-sized piglets" provides evidence on safety and effectiveness of the therapy used in child mode.[2]

The LIFEPAK CR2 delivers the same waveform when treating adults and children, although the amplitude of the pulses reflects the lower energy settings. The Killingsworth article describes testing with shocks generated by the LIFEPAK 12 defibrillator/monitor which delivers shocks with a waveform similar to the shocks generated by the LIFEPAK CR2. In the study, defibrillation thresholds were measured in 10 pigs weighing from 3.8 to 20.1 kg (see Figure 4 below). For adult-sized electrode pads, the defibrillation threshold was 2.1 ± 0.65 J/kg; for pediatric-sized electrode pads, it was 2.4 ± 0.81 J/kg; the difference was not statistically significant.

Figure 4: Defibrillation Thresholds of 10 Pigs

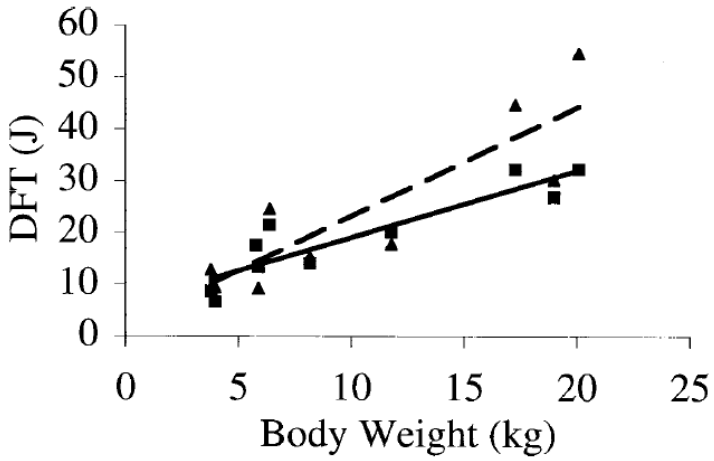


Figure 4 is from Killingsworth article showing defibrillation threshold expressed in energy (Joules) vs. body weight with pediatric-size electrodes (▲) and adult-size electrodes (■). Also shown are regression lines for pediatric (dashed line) and adult (solid line) patches.

The same study also investigated the effect of much larger shocks, with the same waveform, on heart function. Delivering shocks all the way up to the maximum

adult dose of 360 J (without using an attenuator) to these small pigs produced only brief-duration, transient ST-segment, rhythm, and hemodynamic changes. The authors concluded, "Despite the delivery of very large cumulative doses and multiple large individual shocks during the course of each experiment, myocardial function in these small animals was remarkably resilient." This study demonstrates that, with the biphasic waveform employed by the LIFEPAK 12 defibrillator/monitor and the LIFEPAK CR2 defibrillator, there is a large safety factor between the dose needed to defibrillate, and the dose that would cause harm.

The animal study discussed above was leveraged to support the reasonable assurance of safety and effectiveness of the proposed device in the pediatric sub-population of children 1 to 8 years old for the LIFEPAK CR2 defibrillator.

X. SUMMARY OF CLINICAL STUDIES

A new, prospective clinical trial was not conducted using the LIFEPAK CR2 Defibrillator. However, publications of several prior clinical studies[3,4,] conducted by Physio-Control were considered relevant in demonstrating the safety and effectiveness of the LIFEPAK CR2 were provided to support premarket approval**.** In particular, the identical ECG analysis Shock Advisory System and biphasic truncated exponential (BTE) (ADAPTIV biphasic waveform) used in the LIFEPAK 500 defibrillators deployed in the following clinical studies, is also used in the LIFEPAK CR2.

The studies summarized in the PMA are listed in Table 7. Further study details can be found within the summaries of the publications noted below; full citations of the publications are provided in section XV of this SSED.

Table 6. List of Supporting Clinical Studies

Clinical Study #	***Clinical Study***	***Related Publication***
Study #1	Comparison of monophasic vs. biphasic waveforms: in-hospital trial	Higgins, et al., 2000[3]
Study #2	Comparison of monophasic vs. biphasic waveforms: out-of-hospital trial	Van Alem, et al., 2003[4]

A. Clinical Study #1 - Monophasic vs. biphasic waveforms: in-hospital trial[3]

This prospective, double-blinded, randomized clinical trial compared the first shock efficacies of Physio-Control ADAPTIV 200J BTE waveform, 130 J BTE and 200 J monophasic damped sine shocks (MDS) shocks in the electrophysiology lab, delivered from modified LIFEPAK 7 defibrillators (an early defibrillator cleared under 510(k) K810154, but modified to have the same BTE waveform as the LIFEPAK CR Plus and the LIFEPAK EXPRESS).

Methods: VF was induced in 154 patients. After 19±10 seconds of VF, a randomized transthoracic shock was administered. Mean first shock success rates for the three groups were compared.

Results: First shock VF termination rates were 61/68 (90%) for the 200 J monophasic, 39/39 (100%) for the 200 J biphasic, and 39/47 (83%) for 130 J biphasic shocks.

Conclusion: The 200 J biphasic shocks were superior in first-shock effectiveness to both 200 J MDS shocks and 130 J BTE shocks. There were no significant differences in hemodynamic parameters between the three (3) groups after successful shocks. The 200 J biphasic shocks were more effective than monophasic and the 130 J BTE shocks and may allow earlier termination of VF in cardiac arrest patients.

B. **Clinical Study #2 - Monophasic vs. biphasic waveforms: out-of-hospital trial[4]**

In this publication by Van Alem, et al., the authors noted "Evidence suggests that biphasic waveforms are more effective than monophasic waveforms for defibrillation in out-of-hospital cardiac arrest (OHCA), yet their performance has only been compared in un-blinded studies." The authors subsequently conducted and reported on a clinical trial comparing the effectiveness of the LIFEPAK 500 defibrillation waveform (monophasic versus biphasic). Specifically, the success of BTE and MDS shocks for defibrillation were compared in a prospective, randomized, double blind clinical trial of out-of-hospital (OOH) cardiac arrest patients.

Note: The identical ECG analysis Shock Advisory System and BTE (ADAPTIV biphasic waveform) used in the LIFEPAK 500 AED is also used in the LIFEPAK CR Plus and LIFEPAK EXPRESS AEDs.

Methods: First responders were equipped with either a Physio-Control LIFEPAK 500 MDS or BTE (ADAPTIV biphasic waveform) AED in a random fashion. Patients in VF received BTE or MDS first shocks of 200 J. The ECG was recorded for subsequent analysis continuously. The success of the first shock as a primary endpoint was removal of VF and required a return of an organized rhythm for at least two (2) QRS complexes, with an interval of <5 seconds, within 1 minute after the first shock. The secondary endpoint was termination of VF at 5 seconds.

Results: VF was the initial recorded rhythm in 120 patients in OHCA, 51 patients received BTE and 69 received MDS shocks. The median time from collapse to first shock was 9 minutes for the monophasic shock and 11 minutes for the BTE. The success rate of 200 J first shocks was significantly higher for BTE than for MDS shocks, 35/51 (69%) and 31/69 (45%), P=0.01. Termination of VF at 5 seconds after the first shock was 91% for the monophasic shock and 98% for BTE waveform. Return of spontaneous circulation was 61% for the Physio-Control defibrillation shock.

In a logistic regression model, the odds ratio of success for a BTE shock was 4.01 (95% CI 1.01-10.0), adjusted for baseline cardiopulmonary resuscitation, VF-amplitude, and time between collapse and first shock. No difference was found with respect to the secondary endpoint, termination of VF at 5 seconds (RR 1.07 95% CI: 0.99-1.11) and with respect to survival to hospital discharge (RR 0.73 95% CI: 0.31-1.70).

Conclusion: The authors concluded that BTE-waveform AEDs provide significantly higher rates of successful defibrillation with return of an organized rhythm in OHCA than MDS waveform AEDs.

C. **Human Factors**

Human Factors testing was conducted to demonstrate that the LIFEPAK CR2 Defibrillator (semi-automatic and automatic mode) can be used safely and effectively for its indication for use by intended users in its intended use environment. Testing was carried out primarily through simulated use test by having representative users (n=94) perform tasks associated with primary operating functions of the device. The results of testing demonstrated that the LIFEPAK CR2 user interface supports safe and effective use of the device.

D. **Pediatric Extrapolation**

In this premarket application, the applicant submitted the cprINSIGHT algorithm to reduce the pauses between chest compressions in adults and pediatric patients. Because the cprINSIGHT algorithm uses similar measures as the SAS algorithm, it is expected that the cprINSIGHT algorithm will also perform similarly well on both adult and pediatric ECGs. The SAS algorithm performs well for both adult and pediatric ECGs because the ECG measures employed avoid characteristics of the ECG that vary between adults and children.

E. **Financial Disclosure**

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The clinical studies included six (6) investigators of which none were full-time or part-time employees of the sponsor and two (2) investigators had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 1 investigator
- Significant payment of other sorts: 1 investigator
- Proprietary interest in the product tested held by the investigator: none
- Significant equity interest held by investigator in sponsor of covered study: none

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Cardiovascular Device Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel on January 25, 2011 as part of the 515(i) process. The majority of the panel recommended that AEDs be regulated as Class III PMAs to have better oversight of device manufacturing and post-market performance.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. *Effectiveness Conclusions*: The preclinical and clinical information (including commercial use and publications) provided in this PMA did not identify any effectiveness concerns associated with use of the LIFEPAK CR2 (including the battery and QUIK-STEP electrode accessories) for the defibrillators' indications for use.

B. *Safety Conclusions*: The preclinical and clinical information (including commercial use and publications) provided in this PMA did not identify any safety concerns associated with use of the LIFEPAK CR2 (including the battery and QUIK-STEP electrode accessories) for the defibrillators' indications for use.

C. *Benefit-Risk Conclusions*: The LIFEPAK CR2 and accessories (battery and QUIK-STEP electrodes), are new devices not previously cleared by FDA. However, they are in commercial distribution outside the US.

Overall, the information in this PMA demonstrates the safe and effective use of the LIFEPAK CR2 (including the battery and QUIK-STEP electrode accessories) in ongoing, commercial use, for the defibrillators' indications for use and suggests risks in the use of LIFEPAK CR2 defibrillator (and accessories) are outweighed by the benefit of potentially resuscitating cardiac arrest victims.

Patient Perspectives
This application did not include specific information on patient perspectives for the device.

D. In conclusion, the information and data in this application provides reasonable assurance that the LIFEPAK CR2 AED and accessories (battery and QUIK-STEP electrodes) are safe and effective when used in accordance with the indications for use.

XIII. CDRH DECISION

CDRH issued an approval order on December 21, 2018. FDA has developed unique conditions of approval to pursue real world information and in response to panel comments from the 515i Panel discussed in Section XI above. The final conditions of approval cited in the approval order are described below.

The applicant will provide the following non-clinical information as part of the annual report, which may be followed by a PMA supplement, where applicable:

1. The number of devices returned to the applicant for cause from domestic sources, with a breakdown into:
   a. Those returned for normal end-of-life; and
   b. Those returned with any alleged failures or malfunctions, including a summary of root causes and the frequency of occurrence for each identified root cause.

2. The number of replacement defibrillation pads and replacement batteries issued to customers domestically for all causes.

3. A summary of information available to you related to individual domestic uses of your device that may include, but is not limited to:
   a. Defibrillation success and the number of shocks required for success; and
   b. Identification of any error codes or malfunctions during use and their related MDR number.

4. A listing of any safety alerts, technical service bulletins, user communications, or recalls for devices under this PMA.

The applicant will continue to collect data from their OUS Post Market Evaluation Study. The purpose of this post market evaluation is to survey the performance of the LIFEPAK CR2 Defibrillator in the Basic Life Support (BLS) use environment by characterizing the performance of the cprINSIGHT Analysis Technology algorithm, identifying any unanticipated use issues or performance concerns directly attributable to the cprINSIGHT algorithm and collect general device usability data from end users.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, and Cautions in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XV. REFERENCES

The following publications are particularly relevant to the clinical safety and effectiveness of the LIFEPAK CR2.

1) American Heart Association (AHA) Scientific Statement: "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and

Reporting Arrhythmia Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," Circulation 1997; 95:1677-1682.

2) Killingsworth CR, Melnick SB, Chapman FW, Walker RG, Smith WM, Ideker RE, Walcott GP. Defibrillation threshold and cardiac responses using an external biphasic defibrillator with pediatric and adult adhesive patches in pediatric-sized piglets. *Resuscitation* 2002; 55:177-185.

3) Higgins SL, Herre JM, Epstein AE, Greer, SG, Freidman PL, Gleva ML, Porterfield JG, Chapman FW, Finkel ES, Schmitt PW, Nova RC, Greene HL. A Comparison of Biphasic and Monophasic Shocks for External Defibrillation. *Prehospital Emergency Care* 2000;4(4):305-313.

4) Van Alem AP, Chapman FW, Lank P, Hart AAM, Koster RW. A prospective, randomised and blinded comparison of first shock success of monophasic and biphasic waveforms in out-of-hospital cardiac arrest. *Resuscitation* 2003;58(1):17-24.