SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: Automated External Defibrillator

Device Trade Name: Powerheart® G3 Pro AED

Device Product code: MKJ

Applicant's Name and Address: Cardiac Science Corporation
N7 W22025 Johnson Drive, Suite 100
Waukesha, WI 53186

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P160034

Date of FDA Notice of Approval: December 6, 2018

Cardiac Science automated external defibrillators (AEDs) have been on the market in the US since 2003. These devices are currently marketed in the US and globally by Cardiac Science under the brand name Powerheart®. The first Cardiac Science AED branded 'Powerheart' received 510(k) Clearance in 2002 (K011901). The Powerheart® G3 Pro received FDA 510(k) Clearance in 2004 (K040637).

P160034 has been submitted in response to the *Final Order* issued January 29, 2015, in the Federal Register Volume 80 Number 19, Docket No. FDA-2013-N-0234 and republished February 3, 2015, in the Federal Register Volume 80 Number 22, Docket No. FDA-2013-N-0234. The Final Order required premarket approval of marketed pre-amendment Class III Automated External Defibrillators (AED), product code MKJ. Products affected by this Final Order are the Powerheart® G3 Pro (Model number 9000P) AEDs (including the Intellisense® Lithium Battery (Model 9145), Powerheart® G3 AED Defibrillation Pad – Adult (Model 9131), Powerheart® G3 Pro Defibrillation Pads – Adult Polarized (Model 9660), and Powerheart® G3 AED Defibrillation Pad – Pediatric (Model 9730)). A combination of relevant literature, clinical data, animal data, and in-vitro bench testing has been reviewed to demonstrate a reasonable assurance of safety and effectiveness for the Powerheart® G3 Pro AEDs.

II. INDICATIONS FOR USE

The Powerheart® AED G3 Pro is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are:

- unresponsive,
- not breathing normally, and

- without pulse.

When the patient is a child or infant up to 8 years of age, or up to 55 lbs. (25kg), the device should be used with the Intellisense™ Defibrillation Pad – Pediatric. The therapy should not be delayed to determine the patient's exact age or weight.

The Powerheart® AED G3 Pro is intended to be used by personnel who have been trained in its operation.

III. CONTRAINDICATIONS

Cardiac Science AEDs should not be used on patients that are responsive or breathing normally.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions for the Powerheart® G3 Pro AEDs can be found in the labeling.

V. DEVICE DESCRIPTION

Cardiac Science's Powerheart® G3 Pro AEDs (model number 9000P) are portable, battery operated, self-testing defibrillators used to diagnose and treat life-threatening ventricular arrhythmias in patients who are unresponsive and not breathing normally. In addition, electrocardiogram (ECG) display and manual override features are included in the Powerheart® AED G3 Pro. The Powerheart® G3 Pro intended users are professional rescuers.

A patient's ECG is monitored and a defibrillation shock is delivered if necessary. Voice and text prompts provide simple directions to guide the user during a rescue.

AEDs are shipped with defibrillation pads already installed. The Rescue Ready® indicator assures the user that the AED is ready for use.

All models employ an impedance compensating, biphasic waveform.

All models also automatically perform daily, weekly, and monthly self-tests. Self-test results are communicated by audible alert and via the visual Rescue Ready® indicator.

Figure 1: Powerheart® G3 Pro

Batteries

The Powerheart® G3 Pro AED is powered by a user-replaceable, non-rechargeable battery with a 4-year shelf life and 1-year standby life. The Powerheart® AED G3 Pro uses the Intellisense® Lithium Battery (Model 9145). The AED's automatic self-testing detects when the battery is nearing end of life and signals an alert while the unit still retains enough energy to perform a rescue. All batteries are labeled with an expiration date.

Defibrillation Pads

Both adult and pediatric pads are available for use with the Powerheart® G3 Pro AED. The defibrillation pads act as a conductive interface between the AED and the patient's skin. The adult defibrillation pads, Powerheart® G3 AED Defibrillation Pad (Model 9131), are shown in **Figure 2** and the pediatric defibrillation pads, Powerheart® G3 AED Pediatric Defibrillation Pad (Model 9730), are shown in **Figure 3** below.

Figure 2: Adult Defibrillation Pads

Figure 3: Pediatric Defibrillation Pads

VI. ALTERNATIVE PRACTICES AND PROCEDURES

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

VII. MARKETING HISTORY

The Cardiac Science Powerheart® AED G3 Pro has been commercially available in the US and globally since 2004. The STAR® Biphasic waveform and RhythmX® ECG Analysis were first combined in the Powerheart® AED Cleared under K011901 in 2002.

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 device and AEDs in general, listed in decreasing order of seriousness:

- 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 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 NONCLINICAL STUDIES

The Powerheart® G3 Pro AED and accessories underwent bench evaluation, animal testing, biocompatibility evaluation, human factors, and usability testing, as well as software verification and validation appropriate for devices having major level of concern. Testing was conducted on key device subassemblies and the complete systems.

Cardiac Science AEDs are shown to conform to various international standards associated with its AEDs, including:

- IEC 60601-1, General requirements for basic safety and essential performance;
- IEC 60601-1-2, General requirements for basic safety and essential performance – electromagnetic compatibility;
- IEC 60601-1-6, General requirements for basic safety and essential performance – usability;
- IEC 60601-2-4, General requirements for basic safety and essential performance of cardiac defibrillators; and
- IEC 62366, Application of Usability Engineering to Medical Devices.

Bench Testing

Table 1 below summarizes the major bench testing conducted to demonstrate proper performance of the Powerheart® G3 Pro AED, including conformance with applicable consensus performance standards. Pass/fail criteria and deviations from consensus standards were deemed appropriate to the devices considering the specific technological characteristics, intended use, and risk analysis.

Table 1: Bench Testing

	Test Title	Results
1.	Medical Electrical Equipment Safety (IEC 60601-1 3rd edition)	Pass
2.	Particular Requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators (IEC 60601-2-4)	Pass
3.	Particular Requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (IEC 60601-2-27)	Pass
4.	RTCA DO-160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 20, Radio Frequency Susceptibility (Radiated), Category R	Pass
5.	Software Verification and Validation	Pass
6.	Environmental: Ingress (IEC 60529), Temperature Extremes, Humidity and Altitude	Pass
7.	Enclosure Protection (IEC 60529:2001)	Pass
8.	Defibrillation Shock Waveform Testing	Pass
9.	Algorithm Detection Testing	Pass
10.	Integrated System Testing (Combined Hardware and Software)	Pass
11.	Mechanical Hardware Design Verification	Pass
12.	Functional Testing	Pass
13.	Battery Verification and Validation	Pass
14.	Shock and Vibration Testing (MIL-STD 810F)	Pass
15.	Packaging Tests (UN, ISTA)	Pass
16.	Defibrillation Pads Biocompatibility (ISO 10993)	Pass

Biocompatibility Testing

The patient contacting portions of the Cardiac Science AEDs are the electrodes used with the devices. These accessories were tested in accordance with ISO 10993 for cytotoxicity, irritation, and sensitization testing, and passed all testing to adequately demonstrate biocompatibility.

Software Documentation and Validation

Powerheart® G3 Pro AED software was documented and validated according to the FDA guidance document *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* for a major level of concern device. Software 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, unresolved anomaly report, discussion of tools to detect run-time errors, and cybersecurity documentation.

The documentation provided was deemed acceptable for the Powerheart® AED G3 Pro. Software verification and validation testing conducted on each model included unit, integration, and system-level protocols and test reports with pre-defined pass/fail criteria. This testing demonstrated that the software in the Powerheart® G3 Pro performs as intended.

Shelf Life Testing

A sterility review is not necessary because the AEDs, the electrode pads, and the battery are provided non-sterile. Shelf life testing was conducted to demonstrate the labeled shelf life for the defibrillation pads used with the Powerheart® G3 Pro AEDs. Battery life is 4-year shelf life and 1-year standby life. **Table 2** below lists defibrillation pad shelf life information.

Table 2: Defibrillation Shelf Life

Defibrillation Pads	Labeled Shelf Life
G3 Pro Pediatric	27 months
G3 Pro Defibrillation	30 months

Animal Testing

Animal testing was conducted to validate the effectiveness of the Cardiac Science pediatric waveform using Powerheart® pediatric electrodes. The following animal data was collected with the Powerheart AED, which used the same defibrillation waveform of the Powerheart AED G3 Pro.

Powerheart® Defibrillation Success for Short and Long Duration Ventricular Fibrillation

Study objective: Animal study to assess the defibrillation effectiveness of the Powerheart AED Pediatric Electrode System.

Method: Animal testing was performed on a total of seven (7) pigs (domestic crossbreeds) weighing 14 to 24kg. Ventricular fibrillation was induced in the pig and after 15 - 30 seconds VF, a 200J shock was delivered through the attenuator to the electrode. Two (2) additional shocks of 270J were delivered if required for defibrillation. After a minimum of 30 minutes a second episode of ventricular fibrillation was induced in the pig and sustained for 4 minutes.

Results: For short duration VF, the Powerheart® AED could resuscitate five (5) out seven (7) pigs on the first shock, and the remaining two (2) pigs with a second shock. The test results for the fibrillation episode of 4 minutes with simulated CPR were that the Powerheart AED successfully defibrillated all seven (7) pigs with an average of 2.1 shocks ± 1 shock. The average delivered energy was 46.6J ± 3.4J and 59.3J ± 1.2J.

Conclusion: The Powerheart® AED successfully defibrillated all seven (7) pigs for both short and long duration ventricular fibrillation episodes.

X. SUMMARY OF CLINICAL STUDIES

The final order, Effective Date of Requirement for Premarket Approval for Automated External Defibrillator Systems, published on January 29, 2015 and republished on February 3, 2015, states that clinical study information can be leveraged for AEDs from both published studies and clinical data previously submitted to FDA under the 510(k) Premarket Notification process. Cardiac Science submitted the following clinical studies for the original FDA Clearance of the Cardiac Science AEDs.

A. The RhythmX® ECG Analysis and STAR® Biphasic defibrillation waveform

The RhythmX® ECG Analysis and STAR® Biphasic defibrillation waveform was tested during two (2) separate clinical studies, IDE G920078 and IDE G970230.

1. RhythmX® ECG Analysis IDE G920078

Study objective: To prove the effectiveness of the RhythmX® ECG analysis using the Powerheart® Automated External Cardioverter Defibrillator (AECD) device (K011901), which uses the exact same RhythmX® technology as the Cardiac Science's G3 Pro in this PMA.

Method: The study was divided into two (2) phases: Phase I and Phase II. Phase I was further divided into two (2) sub-phases. In Phase I, the Powerheart® AED operated as an arrhythmia detector only and did not deliver shock therapy. Phase I

was not randomized. In Phase II, the Powerheart® AED operated as an arrhythmia detector and optionally delivered shock therapy. Phase II was a blind, randomized trial.

Results: A total of 156 patients were enrolled in the trials. Data from the first 15 patients was excluded because the arrhythmia detection algorithm changed after they were studied. The remaining 141 patients experienced 92 shockable episodes, with 117 patients attached to the Powerheart® AED, and the remaining 24 randomized to the standard of care only. The sensitivity of the Powerheart® AED was 100.0%, the positive predictivity was 93.3%, and the specificity was 99.4%. **Table 3** shows the clinical data of all patients with 95% lower confidence limit scores when attached to the Powerheart® AED.

Table 3: Clinical Data – All Patients Attached to Powerheart® AED

# of Patients	Hours Attached	True Positives	False Positives	True Negatives	False Negatives	Sensitivity	Positive Predictivity	Specificity
117	1138.8	92	6	1065	0	100% (96.8%)	93.9% (88.3%)	99.4% (98.9%)

Conclusion: These data support the conclusion that Powerheart® AEDs accurately detect ventricular tachyarrhythmias and provide appropriate therapy according to physician selected parameters. The data collected demonstrated sensitivity of 100.0%, positive predictivity as 93.9%, and specificity as 99.4%. The initial sample size calculations assumed an expected sensitivity of 90%. The actual sensitivity of 100% calculated in this trial allowed a smaller number of patients to be entered in the study while still providing the necessary high confidence limits. The Powerheart® AED's arrhythmia detection and therapeutic capabilities, as well as its safety and efficacy have been demonstrated with a high confidence level.

Post Market Performance of the RhythmX® Analysis Algorithm

Study objective: Post-market, retrospective study evaluating the field performance of the RhythmX® Algorithm during field uses.

Method: The rescue data from Cardiac Science AEDs was collected between December 1999 and December 2016 from AEDs deployed in various locations globally. All the rescue files represent actual field use of Cardiac Science AEDs (i.e., AED G3 Pro and other models with identical RhythmX Analysis algorithm) during rescue attempts. All reviews and classifications of the ECG rhythm were consistent with the rhythm classifications outlined in Kerber *et al.*,1997[1].

Results: The Performance Goals and Lower Confidence Limit Goals are from the Kerber recommendation. A total 5,522 AED analysis periods were available for evaluation. Exclusions consisted of 592 rhythm segments from AEDs no longer available or supported and not relevant to the performance of RhythmX®. Eight (8) rescues, consisting of 52 separate analysis periods, were rejected due missing or

corrupted ECG data. The results of the analysis of the remaining AED records are summarized in **Table 4**.

Table 4: RhythmX® Results

Rhythms	Goal: Sample Size	Actual: Sample Size	Goal: Performance	Observed: Performance	Goal: 90% One-sided Lower Confidence Limit	Observed: Performance with 90% CI
Shockable						
Course VF	200	1035	>90%	>93%	>87%	>93%
Rapid VT	50	58	>75%	>97%	>67%	>91%
Non-Shockable						
NSR	100	428	>99%	100%	>97%	>99%
AF, SB, SVT, heart block, idioventricular, PVCs, other	30	965	>95%	>96%	>88%	>95%
Asystole	100	1969	>95%	>99%	>92%	>99%
Intermediate						
Fine VF	25	229	Report only	56%	N/A	66%
Other VT	25	9	Report only	100%	N/A	75%
Artifact						
Artifact	N/A	185	Report only	94%	N/A	91%

2. **Adult Defibrillation Waveform: STAR® Biphasic Waveform IDE G970230**

Study objective: To evaluate the first shock effectiveness of monophasic and STAR® Biphasic Waveforms for external defibrillation.

Methods: A prospective, randomized, blinded, multi-center study of 118 patients undergoing electrophysiologic testing or receiving an implantable defibrillator was conducted. Ventricular fibrillation was induced, and defibrillation was attempted in each patient with a biphasic and a monophasic waveform. Patients were randomly placed into two (2) groups: Group 1 received shocks of escalating energy, and Group 2 received only high energy shocks.

Results: The STAR® Biphasic Waveform achieved a first-shock success rate of 100% in Group 1 (95% confidence interval [CI] 95.1% to 100%) and Group 2 (95% CI 94.6% to 100%), with average delivered energies of 201±17J and 295±28J, respectively. The monophasic waveform demonstrated a 96.7% (95% CI 89.1% to 100%) first-shock success rate and average delivered energy of 215±12 J for Group 1

and a 98.2% (95% CI 91.7% to 100%) first-shock success rate and average delivered energy of 352±13J for Group 2. **Figure 4** shows the defibrillation results.

	Group 1		Group 2		Combined	
Variable	**MTE**	**BTE**	**MTE**	**BTE**	**MTE**	**BTE**
Impedance (Ω)	64 ± 19	65 ± 18	65 ± 23	64 ± 22	64 ± 21	65 ± 20
E_D (J)*	215 ± 12	201 ± 17	352 ± 13	295 ± 28	NA	NA
Total no. of first shocks	60	60	55	55	115	115
No. of successful first shocks	58	60	54	55	112	115
First shock success rate (%)	96.7	100	98.2	100	97.4	100
95% CI	89.1-100	95.1-100	91.7-100	94.6-100	92.6-100	97.4-100
E_D - Delivered energy. *Data are shown as average ± SD						

Figure 4: Defibrillation Results

Conclusion: The STAR® Biphasic Waveform was validated in a multicenter clinical trial led by researchers at the Cleveland Clinic and Cedars-Sinai Medical Center. The analysis showed that the overall first-shock defibrillation success rate with the STAR® Biphasic Waveform is statistically higher than the monophasic damped sine or the 150J non-escalating biphasic waveform.

Post-Market Performance of the STAR® Biphasic Waveform

Study Objective: Post-market, retrospective study evaluating the performance of the Powerheart® STAR® Biphasic Waveform during field uses.

Method: The Cardiac Science data from the FirstSave (subsequently discontinued), G3, G3 Plus, and G3 Pro AEDs used for this study were collected from 584 patients between December 1999 and December 2016. All devices used in this study use the same defibrillation waveform, the STAR Biphasic Waveform. The AEDs were deployed in various locations throughout the world. The data were captured from electronic files created by Cardiac Science AEDs during rescue attempts. All rescue files included in these data represent actual field use of Cardiac Science AEDs.

The Cardiac Science retrospective data were collected using a method which limits bias by having minimal exclusion criteria. Cardiac Science allowed any data received from a customer to be included into its database, regardless of the variability in the AED deployment model or resuscitation protocols.

Results: Data were divided into two (2) major groupings. The primary group contains the Cardiac Science data sources broadly identified as Retrospective data. A total of 748 shocks met the inclusion criteria and were available for evaluation. These data were split into four (4) identifiable subgroups. The Complaint data set included 394 shocks and showed shock success of 90% (95% lower CI of 88%). The Fort Worth data set included 164 shocks and showed shock success of 90% (95% lower CI of 86%). The Pittsburgh data set included 97 shocks and showed shock

success of 94% (95% lower CI of 88%). The San Diego data set included 93 shocks and showed shock success of 94% with (95% lower CI of 88%).

The other group included two (2) additional data sets: (1) the Netherlands study, and (2) the Health Club data, that were analyzed with the same inclusion criteria. The Netherlands data set included 249 shocks and showed shock success of 93% (95% lower CI of 89%). The Heath Club data set included 65 shocks and showed shock success of 97% (95% lower CI of 91%).

The data were also pooled for a total of 1,062 shocks that met inclusion criteria and were available for evaluation. Overall results showed shock success of the pooled data as 92% (95% lower CI of 90%). The first shock results showed shock success of the pooled data of 584 shocks as 93% (95% lower CI of 91%). Overall restoration of spontaneous circulation (ROSC)/restoration of an organized rhythm (ROR) was calculated for all 584 patient rescue attempts. Overall ROSC/ROR was 75%.

B. Pediatric Defibrillation

Powerheart® Defibrillation Success for Short and Long Duration Ventricular Fibrillation

Study objective: Animal testing was conducted to validate the effectiveness of the Cardiac Science pediatric waveform using the Powerheart® AED with pediatric electrodes. The Powerheart AED used the same defibrillation waveform, the STAR Biphasic Waveform as the Powerheart G3 Pro.

Method: Animal testing was performed on a total of seven (7) pigs (domestic crossbreeds) weighing 14 to 24kg. Ventricular fibrillation was induced in the pig and after 15 – 30 seconds of VF, a 200J shock was delivered through the attenuator to the electrode. Two (2) additional shocks of 270J were delivered if required for defibrillation. After a minimum of 30 minutes, a second episode of VF was induced in the pig and sustained for 4 minutes.

Results: For short duration VF, the Powerheart AED could resuscitate five (5) out of seven (7) pigs on the first shock, and the remaining two (2) pigs with a second shock. The test results for the fibrillation episode of 4 minutes with simulated CPR were that the Powerheart AED successfully defibrillated all seven (7) pigs with an average of 2.1 shocks ± 1 shock. The average delivered energy was 46.6J ± 3.4J and 59.3J ± 1.2J.

Conclusion: The Powerheart® AED successfully defibrillated all seven (7) pigs for both short and long duration ventricular fibrillation episodes.

C. Pediatric Extrapolation

In this premarket approval application, an animal study was submitted to support the reasonable assurance of safety and effectiveness of the STAR® Biphasic defibrillation

waveform in pediatric patients. The pre-clinical study of the STAR® Biphasic defibrillation demonstrated that this waveform successfully defibrillated all animals for both short and long duration ventricular fibrillation episodes in the pediatric model.

D. Human Use and Usability Studies

Human factors data were collected and analyzed in the Cardiac Science's various usability studies which support the conclusions that the user interfaces for the various AED models, when used by lay users, are safe and effective. The Powerheart® G3 Pro usability study included fifteen (15) participants.

Overall Human Factors Study Approach

The Cardiac Science human factors usability study represents one part of the overall Powerheart® AED validation study plan, which includes the Powerheart G3 Pro AED device.

Intended Users

The Powerheart® G3 Pro AED is intended to be used by:

- **Professional Rescuers/Healthcare Professions (HCPs)—**Personnel trained and certified in emergency services and CPR, and trained in the use of AEDs (e.g., police, fire-fighter, emergency response team, paramedics, emergency medical technician—EMT, security personnel).
- **Professionally trained healthcare personnel/responders** (e.g., nurse, physician), trained and certified in cardiopulmonary resuscitation (CPR), and trained in the use of AEDs.

Cardiac Science anticipates that the HCPs and Professional Rescuers will be trained in CPR and AEDs.

The Powerheart® G3 Pro AED has been found to be safe and effective for the intended users, uses, and use environments. These findings were based of the following results shown in **Table 5.**

Table 5: Powerheart® G3 Pro Usability Study Results

Therapy Function	# of Participants	Shock Delivery Success %	Median time to Shock (seconds)
Adult Mode	14*	100%	53.4
Pediatric Mode	15	100%	65.5
ECG Monitoring mode	15	100%	65.2

*One participant was eliminated in Adult Mode due to study artifact.

E. Complaint Analysis

To further demonstrate the safety and effectiveness of the Powerheart® G3 Pro AED in clinical use, relevant adverse event data were analyzed from January 1, 2015 through March 31, 2018. The results identified two (2) deaths and three (3) malfunctions associated with Powerheart® G3 Pro AED model number 9300P.

For the reported deaths, root cause as determined by Cardiac Science' analysis (regardless if the product was returned or not) and quantity of each cause are: that of the two (2) deaths reported, one (1) was one was related to the battery not being fully seated during use, and one (1) was related to improper handling of pads prior to use.

For the reported malfunctions, the identified root causes and quantities as determined by Cardiac Science are: no fault identified (1), and the device not returned (2).

F. Conclusions

The retrospective analysis of Cardiac Science AEDs in real world use demonstrates effectiveness of the STAR® Biphasic waveform consistent with the cited industry studies. STAR® Biphasic performed well across a representative range of deployment environments. In conclusion, the above data, taken together with the other clinical data and preclinical data analyzed are sufficient to demonstrate safety and effectiveness of the performance of the Powerheart® G3 Pro AED.

G. 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 Financial Disclosure by Clinical Investigators regulation was not provided for this file, as the information leveraged was reviewed for the approval of prior IDEs (e.g., G920078, G970230). Other data included post-market data collected and analyzed by the applicant. Overall, the rationale provided in lieu of formal financial disclosure for this file was acceptable and 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 CLNICAL STUDIES

A. Effectiveness Conclusions

Benefits outweigh the risks with which it is associated. This is verified through the longevity of the commercialization of the products, through the literature on clinical safety and effectiveness, and through the post-market data, including tracking and trending of complaints and vigilance.

B. Safety Conclusions

The preclinical and clinical testing and data collected from the published literature did not identify or result in any unacceptable safety concerns associated with use of the Powerheart® G3 Pro AEDs.

C. Risk-Benefit Determination

The benefit of early defibrillation therapy is the survival of patients in SCA. The time from collapse to defibrillation is critical in-patient survival. For every minute that passes between collapse and defibrillation, survival rates from VF SCA decrease is 7% - 10%.

The magnitude of this benefit is either life or death. Patients are likely to put a high value on this treatment because it has the potential to save their lives. Patients are therefore willing to accept the risks of this treatment to achieve the benefit. If the treatment provides timely successful defibrillation, the patient will (or may) survive a life-threatening cardiac arrest situation and will be able to seek further treatment.

1. Patient Perspectives

   This submission did not include specific information on patient perspectives for this device.

In conclusion, given the available information above, the data support that for patients in sudden cardiac arrest who are unconscious, not breathing, or without circulation the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use.

XIII. CDRH DECISION

CDRH issued an approval order on December 6, 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'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, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XV. REFERENCES

1. RE Kerber, LB Becker, JD Bourland, RO Cummins, AP Hallstrom, MB Michos, G Nichol, JP Ornato, WH Thies, RD White, BD Zuckerman. "Automated External

Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporation New Waveforms, and Enhancing Safety." Circulation (1997), Vol 95, No 6, 1677-1681.