SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Multi-Function Defibrillation Electrodes

Device Trade Name: Kendall™ Multi-Function Defibrillation Electrodes, Medi-Trace™ Cadence Multi-Function Defibrillation Electrodes, Physio-Control/Stryker QUIK-COMBO Pacing/Defibrillation/ECG Electrodes

Device Procode: MKJ

Applicant's Name and Address:
Cardinal Health
777 West Street
Mansfield, MA 02048

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P190007

Date of FDA Notice of Approval: August 07, 2020

II. INDICATIONS FOR USE

The Multi-Function Defibrillation Electrodes are intended to transfer energy from a cardiac defibrillator or pacer to the body of a patient for the purpose of defibrillation, synchronized cardioversion, pacing, or for ECG monitoring.

The Kendall™ and Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes with connectors intended for use with Physio-Control LIFEPAK (LP) defibrillators are compatible with Physio-Control / Stryker LP 15, LP 20, LP 20E, LP 1000, LP CR Plus, and LP Express defibrillators with the exception of the Kendall™ 1010P Adult Multi-Function Defibrillation Electrode, which is compatible with Physio-Control LP 20 and LP 20e defibrillators and the Physio-Control FAST-PATCH® cable.

The Medi-Trace™ Cadence Pediatric Multi-Function Defibrillation Electrodes with connectors intended for use with Physio-Control / Stryker defibrillators are compatible with Physio-Control LP 15, LP 20, and LP 20e defibrillators.

The Kendall™ and Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes with connectors intended for use with ZOLL defibrillators are compatible with

ZOLL R Series BLS, R Series Plus, R Series ALS, X Series, and Propaq MD defibrillators.

The Physio-Control/Stryker QUIK-COMBO Adult pacing/defibrillation/ECG electrodes and QUIK-COMBO Pediatric pacing/defibrillation/ECG electrodes are compatible with LP 15, LP 20, and LP 20e defibrillators. The Physio-Control/Stryker QUIK-COMBO pacing/defibrillation/ECG electrode with REDI-PAK Preconnect system is compatible with LP 15, LP 20, LP 20e, LP 1000, LP CR Plus, and LP EXPRESS defibrillators.

III. CONTRAINDICATIONS

For information on contraindications, refer to the labeling of the compatible defibrillator or pacer.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Kendall™ Multi-Function Defibrillation Electrodes, Medi-Trace™ CADENCE™ Multi-Function Defibrillation Electrodes, Physio-Control/Stryker QUIK-COMBO Pacing/Defibrillation/ECG Electrodes labeling.

V. DEVICE DESCRIPTION

The Kendall™ Multi-Function Defibrillation Electrodes, Medi-Trace™ CADENCE™ Multi-Function Defibrillation Electrodes, Physio-Control/Stryker QUIK-COMBO Pacing/Defibrillation/ECG Electrodes (hereafter the "Cardinal Health Multi-Function Defibrillation Electrodes") are intended for use in defibrillation procedures, cardioversion, pacing, and electrocardiogram (ECG) monitoring. The electrodes transfer energy from a cardiac defibrillator or pacer to the body of a patient for the purpose of defibrillation, synchronized cardioversion, and/or pacing, and may transfer ECG signals from the body of the patient to a cardiac defibrillator/monitor or pacer. The product is intended to be used by trained medical personnel (paramedics, nurses, doctors, etc.) and, if connected to automated external defibrillators (AEDs), by untrained laypersons. The devices are intended for single patient use, are disposable, are sold non-sterile, and are packaged in a sealed pouch. The Cardinal Health Multi-Function Defibrillation Electrodes comprise three types:

1. Adult Composite Multi-Function Defibrillation Electrodes
2. Pediatric Composite Multi-Function Defibrillation Electrodes
3. Adult Tin Multi-Function Defibrillation Electrodes

Table 1 lists the models of Cardinal Health Multi-Function Defibrillation Electrodes included in this PMA application.

Table 1. Defibrillation Electrodes within the Scope of P190007

Trade or Proprietary or Model Name	Model Number	Electrode Type
Kendall 20550 Adult Multi-Function Defibrillation Electrodes, Radiotransparent	20550	Adult, Composite Electrode
Kendall 20770 Adult Multi-Function Defibrillation Electrodes, Radiotransparent	20770	
Medi-Trace Cadence Adult, Multi-Function Defibrillation Electrode, Quik-Combo	22550A	
Medi-Trace Cadence Adult, Preconnect Defibrillation Electrode	22550PC	
Medi-Trace Cadence Adult Multi-Function Quik-Combo Radiotransparent Defibrillation Electrode	22550R	
Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes, Preconnect	22770PC	
Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes, Radiotransparent	22770R	
Quik-Combo Radiotransparent Defibrillation Electrode	PM20003	
Quik-Combo Defibrillation Electrode	PM20005	
Quik-Combo Redi-Pak Preconnect Medtronic Defibrillation Electrode	PM20022	
Medi-Trace Cadence Pediatric Multi-Function Defibrillation Electrodes, Quik- Combo Connector	22550P	Pediatric, Composite Electrode
Medi-Trace Cadence Pediatric Radiotransparent, Defibrillation Electrode	22770P	
Quik-Combo Radiotransparant Pediatric Defibrillation Electrode	PM20012	
Kendall 1010P Adult Multi-function Defibrillation Electrode	31177705	Adult Tin Electrode
Kendall 1310P Adult Multi-function Defibrillation Electrode	31319281	
Kendall 1410Z Adult Multi-function Defibrillation Electrode	31469219	

Adult and Pediatric Composite Multi-Function Defibrillation Electrodes

The Adult and Pediatric Composite Multi-Function Defibrillation Electrodes consist of a pair of disposable electrode pads, either pre-wired with a defibrillator/pacer-specific connector or terminated with a conductive post, provided sealed in a poly foil pouch to retain hydrogel moisture content. An image of a composite electrode is shown in Figure 1.

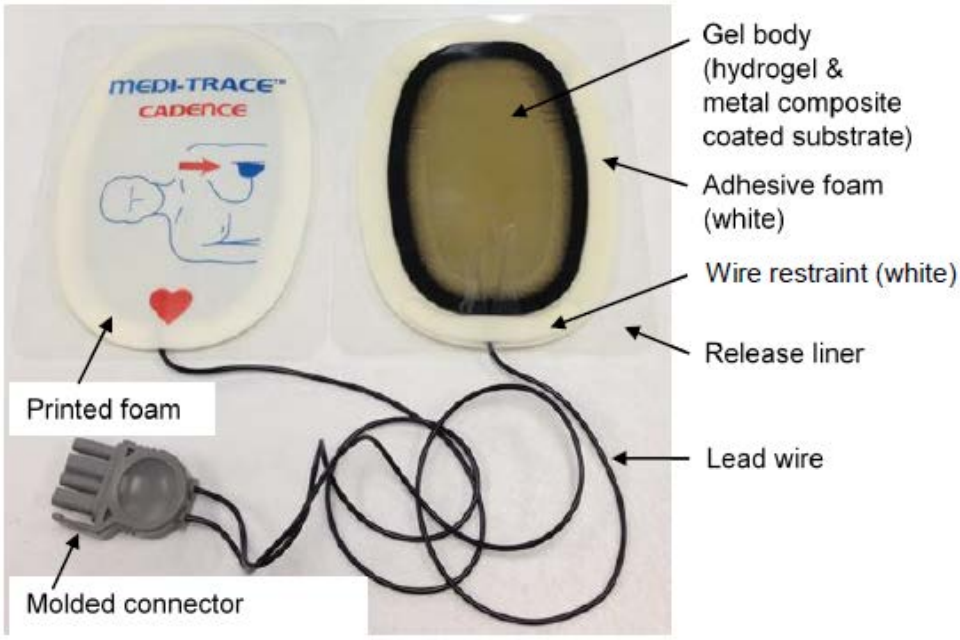

Figure 1. Image of composite multifunction electrode with major external components identified.

The molded connector is fastened to the electrode body and used to attach the electrode to the defibrillator cable. An insulating layer consisting of foam substrate in combination with a polyester film is included over both the conductive mat and the electrode material. A layer of screen-printed metal (silver/silver chloride) composite substrate provides a conductive path to the hydrogel. The conductive adhesive hydrogel adheres to the patient's skin and provides a conductive pathway to the patient's skin. A pressure-sensitive adhesive (PSA) ring at the periphery of the electrode aids adhesion of the electrode to the patient's skin. A release liner protects the conductive adhesive gel before use. The adult and pediatric differ in that the adult electrodes are larger in size than the pediatric electrodes.

The Medi-Trace Cadence composite defibrillation electrodes are designed with an impedance gradient, which is distributed radially outward from the center. The outward gradient electrode distribution helps to reduce the defibrillation current rush from wire termination to electrode edge. Thus, it provides a more even current distribution across the entire electrode gel area. Also, compared to traditional tin electrodes, the composite electrode is considered non-polarizing, nominally charging up after defibrillation shocks. The total amount of composite per electrode dictates pacing performance, and designs with more concentrated electrode composite provide longer pacing durations before the onset of polarization.

The pre-wired products use either metallic or radiotransparent conductor leads with a molded connecter specific to compatible defibrillator types. The specific defibrillators for which each electrode is compatible are listed in the Instructions for Use included with the product. Adult products are labeled with either a 24-month or 30-month shelf life from the date of manufacture and all but one code (non-pacing) is intended for universal

function. All pediatric defibrillation electrodes are intended for universal function and have either an 18-month or 24-month shelf life.

Tin Multifunctional Defibrillation Electrodes

The adult tin electrodes are a pair of disposable electrode pads, either pre-wired with a defibrillator/pacer equipment-specific connector or terminated with a conductive post, sealed in a poly foil pouch to retain hydrogel moisture content. The differences between the adult tin electrodes and the composite electrodes are that the electrodes are composed of tin rather than metal composite and that the design does not include a radially distributed electrode concentration or options for radiotransparency. An image of an adult tin electrode is shown below in the Figure 2.

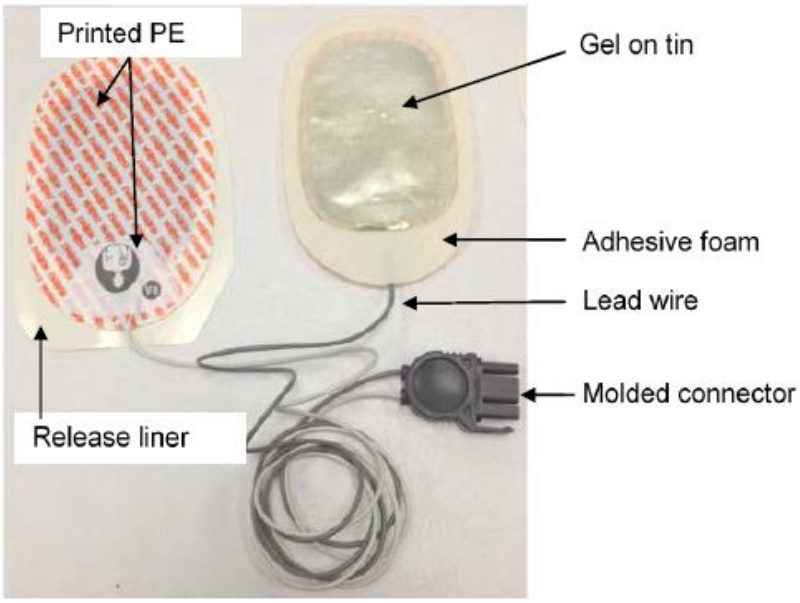

Figure 2. Image of adult tin electrode with major external components identified. PE = polyethylene.

The adult tin defibrillation electrodes are pre-gelled and include a connecting means for attaching the electrode to the lead wire or cable (connector) to attach to the defibrillator. An insulating layer consisting of a vinyl substrate separates the healthcare provider / first responder from the conductive foil. A layer of tin provides a conductive path to the hydrogel. A conductive adhesive hydrogel adheres to the patient's skin, which provides a conductive pathway to the patient's skin. A PSA-coated foam ring at the periphery of the electrode aids adhesion of the electrode to the patient's skin. A release liner protects the adhesive gel before use. The electrode is terminated to either a post or a metal lead wire with a molded connecter specific to compatible defibrillator types. The specific defibrillators for which each electrode is compatible are listed in the instructions for use included with the product. Product is labeled with a 24-month shelf-life from the date of manufacture and is intended for universal function (defibrillation, ECG monitoring, synchronized cardioversion, and transcutaneous pacing).

Two renderings of molded connectors used in two models of defibrillation electrodes are shown in Figure 3 below.

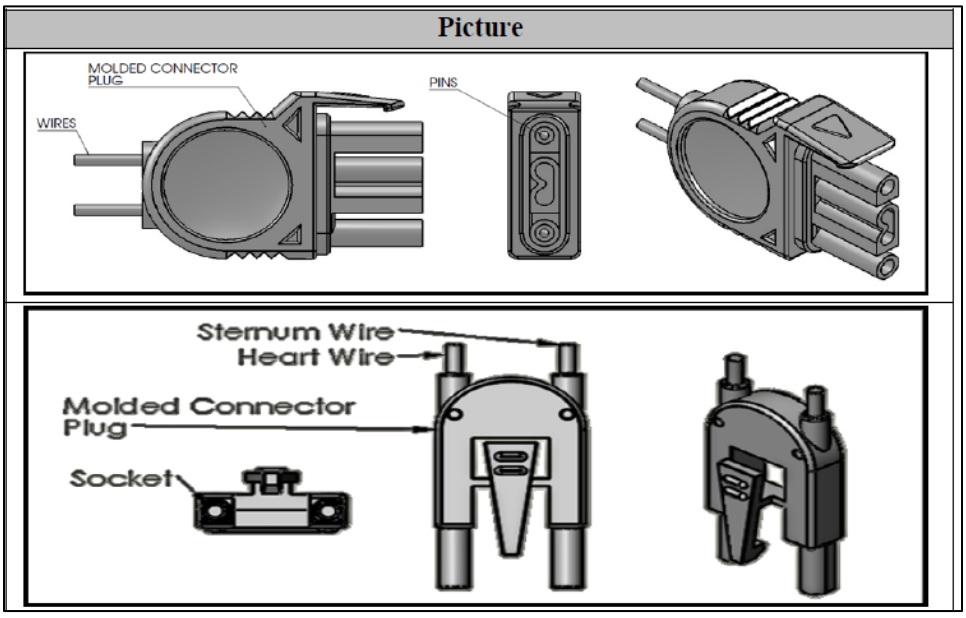

Figure 3: Models of molded connectors

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative products are available for the purpose of defibrillation, synchronized cardioversion, pacing, or ECG monitoring:

- Defibrillation and synchronized cardioversion can be performed using paddles or approved self-adhesive electrodes provided by the original equipment manufacturer (OEM).
- Pacing can be performed using paddles or approved self-adhesive electrodes provided by the original equipment manufacturer (OEM).
- ECG monitoring can be performed using approved self-adhesive electrodes provided by the original equipment manufacturer (OEM). ECG monitoring can also be performed using ECG-specific electrodes.

VII. MARKETING HISTORY

These electrodes have been previously marketed in the US under the following 510(k) submissions:

K955828: Medi-Trace Combination Defibrillation & ECG Electrode for Physio Control Defibrillators. Cleared 07/25/96

K955882: Medi-Trace Combination Defibrillation & ECG Electrode for Hewlett Packard Defibrillators. Cleared 10/24/96
K960329: Disposable Hydrogel Defibrillation Electrode/Pad. Cleared 07/02/96
K970391: Quantum Edge Pediatric Defibrillation Electrodes. Cleared 03/06/97
K980857: Medi-Trace 1310P Combination Defibrillation, Monitoring & Pacing Electrode. Cleared 05/12/98
K012218: Ludlow Gradient Edge Adult & Pediatric Multifunctional Electrodes. Cleared 10/12/01

PMA P190007 was 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.The Kendall™ Multi-Function Defibrillation Electrodes are sold in the United States, Canada, Europe, Middle East, Africa, and Asia Pacific. The MEDI-TRACE™ Cadence Defibrillation Electrodes are sold in the United States, Canada, Europe, Middle East, Africa, Australia, New Zealand, and South America.

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 multifunction defibrillation electrodes include:

- Failure to identify shockable arrhythmia due to poor quality ECG signal.
- 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.
- 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.
- Minor skin rash.

IX. SUMMARY OF NONCLINICAL STUDIES

A. Laboratory Studies

The major bench testing conducted to demonstrate performance of the electrodes, including conformance with applicable consensus performance standards, is shown below in Table 2.

Table 2. Summary of Major Bench Testing

Test Title	Result
Electrical Safety (IEC 60601-1:2015 Edition 3 and IEC 60601-2-4:2010 Edition 3)	Pass
ISTA 2A: 2011 Packaging and Ship (Vibration, Drop etc.) Testing	Pass
Electrode Functional Testing (Electrical and Mechanical), Assembled Electrode, and Connectors	Pass
Defibrillator Compatibility Testing	Pass
High Altitude Packaging Testing	Pass
Packaging Graphics and Electrode Graphics Integrity Testing	Pass
Packaging Testing	Pass

Bench testing comparing the original defibrillator system waveforms to the Cardinal Health system (Cardinal Health (CH) branded defibrillation electrodes with the same original equipment manufacturer (OEM) defibrillator) waveforms to demonstrate that the waveforms were similar.

In addition, bench testing was conducted to compare the OEM defibrillator system waveforms to the Cardinal Health system waveforms and demonstrate that the delivered therapies were similar. The testing included side-by-side oscilloscope captures of the current and voltage waveforms for energies: 2J, 5J, 10J, 30J, 50J, 70J, 100J, 150J, 200J, for both, the Physio-Control and ZOLL defibrillation waveforms and 300J and 360J for the Physio-Control defibrillation waveform. The waveform data was collected for simulated thoracic impedance from 25 ohms to 200 ohms in 25-ohm steps (i.e. 25, 50, 75, 100, 125, ohms, etc.). The following measurements were compared between the OEM system and Cardinal Health system:

a. Peak current of the leading edge of the first and second phase;
b. Peak voltage of the leading edge of the first and second phase;
c. First and second phase duration;
d. First and second phase tilt; and
e. Selected energy and delivered energy.

Differences between the Cardinal Health and OEM delivered energies were evaluated according to accuracy requirements defined in IEC 60601-2-4:2010/A1:2018, subclause 201.12.1 ‘Accuracy of controls and instruments’.

Test Strategy
Cardinal Health selected representative defibrillator and electrode systems to demonstrate compatibility using the following factors:

1) Defibrillator: A representative defibrillator each from Physio-Control and ZOLL Medical was selected after a review of the original manufacturers’ clinical studies presented to support the reasonable assurance of safety and effectiveness of their biphasic waveforms in their respective submissions.

Cardinal therefore chose the models with the greatest amount of selectable energies.

2) Electrodes: Defibrillators measure patient impedance prior to defibrillation discharge and adjust output accordingly. Electrodes with the highest impedance would lead to the greatest output compensation from the target selected energy output, whereas electrodes with the lowest impedance would have the least compensation from the selected output.

The representative electrodes were chosen to bracket the range of Large Signal Impedance (LSI) measurements between the Cardinal Health and OEM electrodes. By comparing the highest LSI electrode in the Cardinal electrode offering to the lowest LSI electrode in the respective OEM offering, the possible extremes in waveform differences were tested with the balance of the Cardinal Health portfolio falling within that bracket.

Physio-Control BTE Waveform Comparison

As described in Physio-Control's Summary of Clinical Studies in P160012 Summary of Safety and Effectiveness Data (SSED) (page 9) and P160026 SSED (page 17-18), The identical BTE (ADAPTIV™ biphasic waveform) used in the LIFEPAK® 500 is also used in the LIFEPAK 1000, LIFEPAK 20e, LIFEPAK 20, LIFEPAK 15, LIFEPAK CR Plus, and LIFEPAK EXPRESS. Therefore, any of these defibrillators could be selected as the representative defibrillator for the Physio-Control waveform comparison. The LP15, LP20, LP20e, and LP1000 are advanced life support devices with twenty-five selectable energy levels compared to the fully automated LP CR Plus and LP EXPRESS, which have fewer energy settings. As such, the LP20e unit was used in both Cardinal Health and OEM system waveform tests to examine defibrillation electrode differences. Selection of the representative test sample electrodes was based on LSI. There are many factors that influence electrode LSI (e.g., hydrogel area/size, composition of the hydrogel formulation, conductive substrate material composition, lead wire conductor materials), therefore direct measurement of LSI per IEC 60601-2-4:2010/A1:2018 subclause 201.108.1.2 was used to define the test sample groups. Cardinal Health's pediatric radiotransparent (RTS) electrodes, with Ag/AgCl ink printed on carbon substrate paired with carbon lead wire conductors and small hydrogel area, generate the highest impedance of all electrodes in the Cardinal Health portfolio. Physio-Control's tin-based electrode has the lowest impedance (Table 3). Thus, the 22550P Medi-Trace Cadence pediatric electrode was designated as the representative electrode for all compatible Cardinal Health branded electrodes and the Physio-Control 3200727-005 QUIK PAK electrode was used for the OEM system. Table 3 provides a list of the Adult electrodes that fall within this bracket and thus did not require separate testing.

Table 3. Defibrillation electrodes for Physio-Control

Item No.	Description
31319281	Kendall Adult, 1310P
31177705	Kendall Adult, 1010P
3200727-005	Physio-Control Quik Pak
22550PC	Medi-Trace Cadence Adult Preconnect
3202674-005	Physio-Control Redi Pak, PM20022
22550A	Medi-Trace Cadence Adult
3010188-021	Physio-Control Quik Combo Connector, Adult, PM20005
22550R	Medi-Trace Cadence Adult RTS
3010188-020	Physio-Control QC Connector, RTS Adult, PM20003
3010107-006	Physio-Control Quik Combo (QC) Connector, Pediatric, PM20012
20550	Kendall Adult Radiotransparent (RTS)
22550P	Medi-Trace Cadence Pediatric

ZOLL RLB Waveform Comparison

The ZOLL R Series® and X Series® models all utilize the same defibrillation waveform, which was also used on the M Series biphasic defibrillator. Clinical data supporting safety and efficacy of ZOLL's rectilinear biphasic waveform was first presented to the FDA in the M Series biphasic defibrillator K990762 (P160022 SSED -page 27). In addition, the Device Description of P160022 stated the Propaq MD is an alternate configuration of the X Series that was developed by making insignificant changes to the cleared X Series. The R Series has three different models: R Series ALS, R Series BLS and R Series Plus. All three models are essentially identical from a hardware standpoint, except for the difference in the front panel assembly, and use the same software. Of the five previously mentioned defibrillator models, the X Series was chosen as the representative defibrillator for the ZOLL waveform tests. Representative test sample electrodes for the Cardinal Health system have the highest impedance within the Cardinal Health defibrillation electrode portfolio following the same reasoning as the Physio-Control waveform comparison. Correspondingly, ZOLL's lowest impedance electrode was used for the OEM system (Table 4). Therefore, the 22770P Medi-Trace Cadence pediatric electrode was designated as the representative test sample electrode for all Cardinal branded electrodes and the lowest impedance electrode of the ZOLL product portfolio was the 8900-0402 CPR Stat-padz, which was used for the OEM system. Table 4 provides a list of the Adult electrodes that fall within this bracket and thus did not require separate testing.

Table 4. Defibrillation electrodes for ZOLL

Item No.	Description
31469219	Kendall Adult, 1410Z
8900-0402	CPR Stat-Padz HVP
8900-0224-01	OneStep CPR Complete
8900-0801-01	Stat-Padz II HVP
8900-4004-01	Stat-Padz HVP
22770PC	Medi-Trace Cadence Adult Preconnect
8900-0223-01	OneStep CPR Resuscitation
8900-0221-01	OneStep Basic
8900-0222-01	OneStep Pacing
8900-0225-01	OneStep CPR AA
8900-4006-01	Pro-Padz Solid Gel Radiolucent
8900-0800-01	CPR-D Padz
8900-1007-40	Pedi-Padz Solid Gel Radiolucent
22770R	Medi-Trace Cadence RTS Adult
8900-3001-40	Pedi-Padz Solid Gel
8900-0810-40	Pedi-Padz II
8900-0218-40	OneStep Pediatric Resuscitation
20770	Kendall RTS Adult
8900-2302-01	Pro-Padz Biphasic
8900-2106-01	Pro-Padz Liquid Gel Radiolucent
22770P	Medi-Trace Cadence Pediatric
8900-2061	Pedi-Padz

Summary results

Bench testing comparing the original defibrillator system waveforms to the Cardinal Health system (Cardinal Health branded defibrillation electrodes with same OEM defibrillator) waveforms demonstrated that the delivered therapy was the same. The side-by-side comparisons showed that the OEM and Cardinal Health waveshapes were similar and that the difference between Cardinal Health and OEM delivered energies were all within the pre-specified defibrillator energy accuracy requirement of ± 15 %.

Biocompatibility Testing

The electrodes were tested in accordance with ISO 10993 for cytotoxicity, irritation, and sensitization. The electrodes passed all testing to adequately demonstrate biocompatibility.

Sterilization and Shelf Life

No parts of this device or any of its components are provided sterile.

The shelf life of the device is driven by the electrode material and the devices were tested in compliance with IEC 60601-2-4:2010. The standard accelerated testing procedure at higher temperature was used.

For Adult Composite Electrodes, 60 samples underwent accelerated testing with a target of 24 or 30 months, depending on the model, as shown in the table below.

Table 5. Adult Composite Electrodes Shelf Life

Model	**Shelf Life (Months)**
Kendall 20550 Adult Multi-Function Defibrillation Electrodes, Radiotransparent	24
Kendall Adult Multi-Function Defibrillation Electrodes, Radiotransparent	24
Medi-Trace Cadence Adult, Multi-Function Defibrillation Electrode, Quik-Combo	24
Medi-Trace Cadence Adult, Preconnect Defibrillation Electrode	24
Medi-Trace Cadence Adult Multi-Function Quik-Combo Radiotransparent Defibrillation Electrode	24
Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes, Preconnect	24
Medi-Trace Cadence Adult RTS Connector Multi-Function Defibrillation Electrodes	24
Quik-Combo Radiotransparent Defibrillation Electrode	30
Quik-Combo Defibrillation Electrode	30
Quik-Combo Redi-Pak Preconnect Defibrillation Electrode	30

After accelerated aging, the samples underwent the following functional testing:

- Visual inspection
- Single Directional Peel
- Small Signal Impedance (30 kHz and 10 Hz)
- DC Offset Voltage
- Large Signal Impedance
- Defibrillation Recovery

All samples passed the post-aging testing without any deviations.

For the Pediatric Composite Electrodes, 60 samples underwent accelerated testing with a target of 18 and 24 months depending on the model, as shown in the table below.

Table 6. Pediatric Composite Electrodes Shelf Life

Model	Shelf Life (Months)
Medi-Trace Cadence Pediatric Multi-Function Defibrillation Electrodes, Quik- Combo Connector	24
Medi-Trace Cadence Pediatric Radiotransparent Connector, Defibrillation Electrode	24
Quik-Combo Radiotransparant Pediatric Defibrillation Electrode	18

After accelerated aging, the samples were tested to verify the following functional performance:

- Visual inspection
- Single Directional Peel
- Small Signal Impedance (30 kHz and 10 Hz)
- DC Offset Voltage
- Large Signal Impedance
- Defibrillation Recovery

All samples passed the post-aging testing without any deviations.

Finally, for the Adult Tin Electrodes, 30 samples underwent accelerated testing with a target of 24 months as shown in the table below.

Table 7. Adult Tin Electrodes Shelf Life

Model	Shelf Life (Months)
Kendall 1010P Defibrillation Electrode	24
Kendall 1310P Defibrillation Electrode	24
Kendall 1410Z Defibrillation Electrode	24

After accelerated aging, the samples were tested to verify the following functional performance:

- Visual inspection
- Single Directional Peel
- Small Signal Impedance (30 kHz and 10 Hz)
- DC Offset Voltage
- Combined offset instability and Noise
- Large Signal Impedance
- Defibrillation Recovery

All samples passed the post-aging testing without any deviations.

B. Animal Studies

No animal studies were conducted to support this PMA.

C. Additional Studies

Human Factors

Human Factors testing was not required to support approval of this PMA.

Cardinal Health performed a Use-Related Risk Analysis, performed a Task Analysis and identified the Critical Tasks associated with the scenario where the user interface differs between the subject device and the electrode already included in the AED. Each task included the following: Task description, Potential use error associated with the task, Hazard/harm associated with each use error, Severity level of the harm, Critical task (Yes/No) and Risk mitigation measure for the use error.

The use-related risks included:

- Subject device connector does not mate with the Defibrillator.
- Subject device not compatible with Defibrillator software.

Risk analysis of the defibrillation electrodes was performed in accordance with EN ISO 14971:2012 (Medical devices - Application of risk management to medical devices).The residual risk summary shows that the residual risk is as low as possible.

As part of the mitigation plan, Cardinal Health developed a *Defibrillator Electrode Compatibility Assurance Plan* which contains information on how the use-related risks are to be mitigated when there is no quality agreement between Cardinal Health and the defibrillator manufacturer. The plan includes periodic compatibility assessments by a third-party lab. The compatibility assessment data will be input into production and post-production surveillance and will include human factor evaluation and risk analysis.

Cardinal Health will also conduct post-market surveillance of the OEM defibrillators to mitigate the risks of unknown compatibility issues for AEDs with whom Cardinal Health does not have an agreement. Monitoring includes review of the FDA's MAUDE Database, FDA's PMA Approval Database, Literature Databases, Nerac, and Embase.

Perspiration Test of Defibrillation Electrodes

A study was performed in order to document the effects of perspiration on defibrillation electrodes and to support activities related to this PMA submission. The study was conducted to IEC 60601-2-4, Subclause 201.108.1.8, which states that data on the adhesive response to perspiration should be available. In order to determine the duration of use for defibrillation electrodes on human skin, studies were performed on human subjects using defibrillation electrodes manufactured by Cardinal Health.

The study was a single-center, prospective evaluation to examine the responses of the foam adhesive, hydrogel, and total electrode lift of defibrillation electrodes to perspiration. A minimum of 20 subjects, 10 female, were used for the study. The subjects were enrolled in one of two groups consisting of five men and five women to evaluate two sets of electrodes for a total of four electrodes per subject covering all four products for a minimum of 10 minutes per subject. Ten (10) minutes was needed to cover five shocks and four two-minute attempts at CPR per the 2015 AHA guidelines for CPR and Emergency Cardiovascular Care.

The study involved the subjects being exposed to a temperature of approximately 100 °F with hot water turned on to simulate approximately 80% humidity for 10-15 minutes until the subject was sweating. Subjects were then prepped and electrodes were attached per the Instructions for Use. An ECG trace was obtained at initial placement and after a minimum of 10 minutes. The study was deemed successful if an ECG trace was obtained after a minimum of 10 minutes.

The results of the study demonstrated that the adhesive materials used in the defibrillation electrodes have sufficient adhesive performance to adhere to skin with perspiration. An acceptable ECG was obtained for each subject at the time of initial placement, and a subsequent ECG trace was obtained after a minimum of 10 minutes. No adverse events were reported during the study.

Duration of Use on Human Skin

In order to determine the duration of use for defibrillation electrodes on human skin, studies were performed on human subjects using defibrillation electrodes manufactured by Cardinal Health. The primary objective of the evaluation was to provide duration of use test data regarding the percent lift of the hydrogel, foam adhesive, and total electrode lift after 30 hours of wear by 10 subjects, 5 female, with a minimum of 20 electrodes tested (10 sets per product type) tested.

In addition to an evaluation of the degree of skin irritation or trauma caused by the electrodes following the testing, the acceptance criteria for the testing was as follows:

- Adhesive/hydro-gel retention attributes of electrodes will be maintained over a period of normal to exaggerated use (30 ± 1 hour).
- Electrodes will provide a readable ECG trace following duration of use test.

Both studies met the pre-specified acceptance criteria for the determination of duration of use for defibrillation electrodes on human skin with both a normal and an exaggerated use time period of 30 ± 1 hours.

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) process. Cardinal Health submitted a comparison of the original defibrillator system waveforms (Physio-Control and ZOLL) to the Cardinal Health Multi-Function Defibrillation Electrodes with the same original equipment manufacturer (OEM) defibrillator waveforms. The waveform delivered by Physio-Control/Stryker, ZOLL, and Cardinal Health electrodes is a biphasic truncated, impedance-compensating exponential waveform. The comparison consisted of oscilloscope captures of the adult and pediatric defibrillation waveforms. The waveforms were collected from 25 ohms to 200 ohms in 25 ohms steps. The following electrical parameter measurements and calculations were also included:

a) Peak current of the leading edge of the first and second phase
b) Peak voltage of the leading edge of the first and second phase
c) First and second phase duration
d) First and second phase tilt
e) Selected energy and delivered energy

The waveform data provided by Cardinal Health demonstrates that the adult and pediatric waveforms from Cardinal Health Multi-Function Defibrillation Electrodes compared to Physio-Control and ZOLL AED systems were sufficiently similar to support leveraging of data to demonstrate a reasonable assurance of safety and effectiveness. Consequently, the clinical data included in this submission was leveraged from published clinical data[2,3,4] for adult and pediatric uses of the Cardinal Health Multi-Function Defibrillation Electrodes.

A. Published Clinical Data

For Cardinal Health Multi-Function Defibrillation Electrodes claiming compatibility to Physio-Control/Stryker defibrillators, the following studies were leveraged:

Higgins et al. [2] A Comparison of Biphasic and Monophasic Shocks for External Defibrillation.

Primary endpoint: To compare the efficacies of first shocks of 200-J monophasic, 200-J biphasic, and 130-J biphasic waveforms administered to terminate ventricular fibrillation (VF).

Study design: Prospective, randomized, double-blind, multicenter clinical trial.

Methods: Patients included in the study were 18 years of age or older undergoing electrophysiologic testing for ventricular arrhythmias or for evaluation of an Implantable Cardioverter Defibrillator (ICD). Patients were excluded on the basis of having a right-sided pectoral ICD or if they had intrathoracic or subcutaneous patch or array electrodes. As part of the

electrophysiology (EP) testing, ventricular tachycardia (VT) or ventricular fibrillation (VF) was induced by programmed stimulation, burst ventricular stimulation or synchronized T-wave shock via implanted or temporary right ventricular electrodes. Transthoracic defibrillation shocks were generated by a study device (LIFEPAK 7, Physio-Control Corp.) and delivered through disposable pacing/defibrillation/ECG electrodes (QUIK-COMBO, Physio-Control Corp., Redmond, WA).

Ventricular fibrillation (VF) was induced in 115 patients during evaluation of implantable cardioverter–defibrillator function and 39 patients during electrophysiologic evaluation of ventricular arrhythmias for a total of 154 patients. After 19 ± 10 seconds of VF, a randomized transthoracic shock was administered.

Results: In the 200-J monophasic group, 61 out of 68 (89.7%) of the first shocks successfully terminated VF. In the 200-J biphasic group, 39 out of 39 (100%) of the first shocks terminated the VF. And in the 130-J biphasic group, 39 out of 47 (83%) of the first shocks terminated the VF.

Conclusion: The 200-J biphasic shocks were statistically superior in first shock termination of VF to both the 200-J monophasic and the 130-J biphasic shocks. The authors conclude that the 200-J biphasic shocks may allow earlier termination of VF in cardiac arrest patients.

Van Alem et al.[3] A prospective, randomised and blinded comparison of first shock success of monophasic and biphasic waveforms in out-of-hospital cardiac arrest.

Primary endpoint: Termination of VF and return of organized rhythm for at least two QRS complexes of similar morphology in the span of less than 5 seconds, within one minute of the first shock for out-of-hospital cardiac arrest (OHCA) events.

Study design: Prospective, randomised and blinded

Methods: From January 2000 to June 2002, 217 patients in Amsterdam, NL and the surrounding area with OHCA participated in the study. Forty LIFEPAK 500 MDS (monophasic damped sinusoidal) AEDs and forty LIFEPAK 500 BTE (biphasic truncated exponential) AEDs were randomly provided to EMS units. The first responders provided CPR while the AED was being prepared. If shocks were required, they were administered using a 200 J, 200 J, 360 J shock sequence.

Results: 120 patients with recognized VF and delivered shock were analyzed. 69 patients received MDS shocks and 51 received BTE shocks. First shock success in terminating VF was 1.5 times greater for the BTE waveform group

(69%) compared to the 45% success rate of the MDS group (P=0.01). Success rates for termination of VF within 5 seconds post-shock (the secondary end point) were not significant (P=0.12) nor were the rates of ROSC (P=0.62) between groups. Logistic regression of first shock success demonstrated an odds ratio of 4.0 for the BTE group versus the MDS group, after adjusting for bystander CPR, VF amplitude and time to first shock (95% confidence interval 1.67 – 10.0, P=0.002).

Conclusion: AEDs with the BTE waveform had significantly higher rates of success with return of organized rhythm in OHCA than the AEDs with MDS waveforms.

For Cardinal Health Multi-Function Defibrillation Electrodes claiming compatibility to ZOLL defibrillators, the following study was leveraged:

Hess et. al.[4], Performance of a rectilinear biphasic waveform in defibrillation of presenting and recurrent ventricular fibrillation: a prospective multicenter study.

Primary endpoint: To assess the performance of the rectilinear biphasic waveform (RLB) waveform using a non-escalating low-energy protocol for the first 3 shocks and to assess performance for subsequent shocks.

Study Design: Prospective multicenter study

Methods: From September 2008 to March 2010 out-of-hospital cardiac arrest patients (Adults ≥18 years of age) with ventricular fibrillation (VF) as the initial rhythm at 9 study sites were defibrillated by paramedics using an RBL. (Note: Patients were considered to have VF as the initial rhythm if a shock was delivered by a first-responder automated external defibrillator (AED) prior to arrival of paramedics or when AED ECG data were available for review and VF was documented.) Shock success was defined as termination of VF within 5 s post-shock. Generalized estimating equation (GEE) analysis to assess the association between shock type (initial versus defibrillation) and shock success.

Results: Ninety-four (94) patients presented in VF. Mean age was 65.4 years, 78.7% were male, and 80.9% were bystander-witnessed. VF recurred in 75 (79.8%). There were 338 shocks delivered for initial (n = 90) or recurrent (n = 248) VF available for analysis. Initial shocks terminated VF in 79/90 (87.8%) and subsequent shocks in 209/248 (84.3%). GEE odds ratio (OR) for shock type was 1.37 (95% CI 0.68–2.74). After adjusting for potential confounders, the OR for shock type remained insignificant (1.33, 95% CI 0.60–2.53). There was no observed significant difference in restoration of spontaneous circulation (ROSC) (54.7% versus 52.6%, absolute difference 2.1%, p = 0.87) or neurologically intact survival to hospital discharge (21.9% versus 33.3%,

absolute difference 11.4%, p = 0.31) between those with and without VF recurrence.

Conclusion: Presenting VF was terminated with one shock in 87.8% of cases. No significant difference in the frequency of shock success between initial versus recurrent VF was observed. VF recurred in the majority of patients and did not adversely affect shock success, ROSC, or survival.

B. Pediatric Defibrillation

The waveform data provided by Cardinal Health demonstrates that the pediatric defibrillation waveforms from Cardinal Health electrodes compared to Physio-Control and ZOLL AED systems were similar. Consequently, the animal data that was used to support the approval of pediatric defibrillation by Physio-Control and ZOLL was fully leveraged for the Cardinal Health pediatric defibrillation electrodes.

For pediatric defibrillation electrodes claiming compatibility to the Stryker/Physio-Control defibrillators the R.A. Berg et al. animal study [Attenuated adult biphasic shocks compared with weight-based monophasic shocks in a swine model of prolonged pediatric ventricular fibrillation] was leveraged.[5] In this study, the safety and effectiveness of monophasic 2-4 J/kg and attenuated biphasic shocks (ADAPTIV Biphasic waveform) were studied in the resuscitation of 48 immature swine from 7 minutes of untreated ventricular fibrillation. The weights of the animals studied were representative of the weights of newborn, 3-year-old, and 8-year-old children. In this animal model of pediatric cardiac arrest, the attenuated biphasic shocks were superior to the monophasic 2-4 J/kg shocks in two (2) ways: (1) they provided a significantly higher survival rate and (2) they were associated with significantly better cardiac function 4 hours after the cardiac arrest. Furthermore, fewer biphasic than monophasic shocks were required during the resuscitation of these animals.

Cardinal Health leveraged two animal studies for their pediatric defibrillation electrodes claiming compatibility to the ZOLL pediatric defibrillation electrodes. The two animal studies were published in the Summary of Safety and Effectiveness Data (SSED) for ZOLL's PMA P160015. In brief, one study included 18 piglets weighing from 8 kg to 16 kg) and compared the defibrillation dose/response curves observed using rectilinear biphasic waveform with those observed using monophasic damped sine waveforms to treat short duration (~ 30 seconds) ventricular fibrillation. The study demonstrated that the rectilinear biphasic waveform defibrillates pediatric pigs with equal efficacy but lower energy (on a Joules/kg basis) than monophasic damped sine wave defibrillators.

Another animal study compared the ZOLL rectilinear biphasic (RLB) waveform to a biphasic truncated exponential (BTE) waveform. The study, using an immature porcine model (n=21), was a prospective, randomized, controlled design to determine the dose response curves for the RLB and BTE defibrillation waveforms.

A weight range from 4 to 24 kg for an animal represented a pediatric patient. The ZOLL RLB waveform demonstrated a statistically superior capability to defibrillate a porcine pediatric model with < 90% of the D50 energy required for a BTE waveform (D50 energy: RLB 25.6 ± 15.7 J, BTE 28.6 ±17.0 J, $P \leq 0.0232$; D90 energy: RLB 32.6 ± 19.1 J, BTE 37.8 ± 23.2 J, $P \leq 0.0228$).

C. 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. There was no pivotal clinical study. None of the clinical investigators in the leveraged studies had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f).

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

To further demonstrate the safety and effectiveness of the devices in clinical use, relevant complaint data were analyzed since 2013. For the Adult composite Kendall™ Multifunction Defibrillation Electrodes and MEDI-TRACE™ Cadence Defibrillation Electrodes. A total of 156 complaints were reported from October 2013 to September 2018. The overall complaint rate was 0.0012%, and the reportable complaint rate was 0.00053% for the period of October 2013 to September 2018. For the pediatric composite Kendall™ Multifunction Defibrillation Electrodes and MEDI-TRACE™ Cadence Defibrillation Electrodes, only two complaints were reported with pediatric products during this timeframe. Overall this represents a 0.00026% complaint rate. None of the complaints were reportable. For the tin Kendall™ Multifunction Defibrillation Electrodes and MEDICHOICE® Multifunction Electrodes, a total of 37 complaints were reported from October 2013 to September 2018 for an overall complaint rate of 0.0014% and reportable complaint rate of 0.00042%.

XII. 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 Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

Two major functions of the multifunction electrodes are to deliver or transmit an electrical shock/signal, and to remain adhered to the patient in order to serve as the

conduit to deliver or transmit an electrical shock/signal. The former is addressed through nonclinical studies (refer to Section IX), while the latter has been addressed through wear studies conducted as part of the clinical investigations (refer to Section X).

Reasonable assurance of the effectiveness of the Kendall™ Multi-Function Defibrillation Electrodes, Medi-Trace™ Cadence Multi-Function Defibrillation Electrodes, Physio-Control/Stryker QUIK-COMBO Pacing/Defibrillation/ECG Electrodes for the stated indications for use has been supported in this PMA with data from nonclinical studies including bench testing, and defibrillator waveforms testing, biocompatibility and shelf life studies (refer to Section IX).

- Design verification reports illustrate Cardinal Health's defibrillation electrodes' conformance to the minimum performance requirements of 60601-2-4 201.108.1, demonstrating the ability to perform essential defibrillation electrode function (transmit defibrillation therapy and ECG signals).

- Bench testing comparing the original defibrillator system waveforms to the Cardinal Health branded defibrillation electrodes (adult and pediatric) with the OEM defibrillator waveforms demonstrated that the waveforms were similar.

Additionally, two human studies were also conducted to support the reasonable assurance of safety and effectiveness of the subject devices (refer to Section X).

- Conclusions from the *Perspiration Test of Defibrillation Electrodes* confirm that the adhesive materials used in the defibrillation electrodes have sufficient adhesive performance to adhere to skin with perspiration. No adverse events were reported during the study. The ability to collect an ECG trace indicates that the contact to the skin is sufficient. The adhesive materials used in the defibrillation electrodes have sufficient adhesive performance to adhere to skin with perspiration.

- The *Determination of the Duration of Use for Defibrillation Electrodes on Human Skin* study conducted to determine the duration of use for defibrillation electrodes (Composite Electrodes and Tin Electrodes) on human skin evaluated the percent lift of the hydrogel, foam adhesive, and total electrode lift after 30 hours of wear. The acceptance criteria required that the adhesive / hydrogel retention attributes of electrodes were to be maintained over a period of normal to exaggerated use (30 +/- 1 hour), and electrodes would provide a readable trace following the duration of use test. The acceptance criteria were met.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory testing and clinical studies in addition to substantial worldwide commercial use for over two decades coupled

with post-market surveillance information. Data collected did not identify unacceptable safety concerns associated with use of the Kendall™ Multi-Function Defibrillation Electrodes, Medi-Trace™ Cadence Multi-Function Defibrillation Electrodes, Physio-Control/Stryker QUIK-COMBO Pacing/Defibrillation/ECG Electrodes for the stated indications for use.

C. Benefit-Risk Determination

Kendall™ Multi-Function Defibrillation Electrodes, Medi-Trace™ Cadence Multi-Function Defibrillation Electrodes, Physio-Control/Stryker QUIK-COMBO Pacing/Defibrillation/ECG Electrodes were previously FDA-reviewed and cleared under 510(k) notifications for their current indications for use. The devices have been in commercial distribution within the United States and numerous worldwide countries for more than two decades.

The probable benefits and risks of the device are based on the published literature, clinical investigations, human factors studies, and post-market clinical data, which were collected after 510(k) clearance as described above.

The benefit of early defibrillation therapy is survival of patients in cardiac arrest, and multifunction defibrillation electrodes serve as the conduit to deliver or transmit therapeutic electrical current. AEDs and their electrode accessories are life-saving devices used in emergency situations. They have been shown to have a high benefit for patients with underlying diseases that remain undetected until sudden cardiac arrest (SCA) occurs. The time from collapse to defibrillation is critical to patient survival. For every minute that passes between collapse and defibrillation, survival rates from VF SCA decrease 7% to 10%.

The magnitude of this benefit is either life or death. The published literature, clinical investigations/human factors studies, and post-market clinical data are unable to predict which patients will experience a benefit or determine probability of benefit due to the differing pathophysiology of underlying cardiac arrest. The subpopulations have a high degree of heterogeneity of etiologies of cardiac arrest, so variation in public health benefit cannot be determined. Additionally, the duration of effect is dependent on underlying etiology and, while valuable to the patient, is highly dependent on subsequent treatment of the underlying disease. Duration of effect is not related to the device.

Patients put a high value on this treatment as 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 survive a life-threatening cardiac arrest situation and will be able to seek further treatment. Cardinal Health will be conducting post-market surveillance of the defibrillators to mitigate the risks of unknown compatibility issues for AEDs with whom Cardinal Health does not have an agreement. Monitoring includes review of

the FDA's MAUDE Database, PMA Approval Database, Literature Databases, Nerac, and Embase.

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

In conclusion, given the available information above, the probable benefits outweigh the probable risks for the Kendall™ Multi-Function Defibrillation Electrodes, Medi-Trace™ Cadence Multi-Function Defibrillation Electrodes, Physio-Control/Stryker QUIK-COMBO Pacing/Defibrillation/ECG Electrodes for the stated indications for use.

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. For patients in cardiac arrest who are unconscious, not breathing, without circulation, or require transcutaneous pacing or ECG monitoring, the probable benefits outweigh the probable risks.

XIV. CDRH DECISION

CDRH issued an approval order on August 07, 2020.

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

XV. 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.

XVI. REFERENCES

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