

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Defibrillator electrode Pads and Accessory Cables/Connectors

Device Trade Name: TZ Medical Adult Multi-Function Defibrillation Electrodes and Adaptors and TZ Medical Pediatric Multi-Function Defibrillation Electrodes and Adaptors

Device Procode: MKJ

Applicant's Name and Address: TZ Medical, Inc
17750 SW Upper Boones Ferry Rd #150
Portland, OR 97224

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P200005

Date of FDA Notice of Approval: 1/09/2024

II. INDICATIONS FOR USE

TZ Medical disposable electrodes are intended for use by trained professionals in hospitals, doctor's offices and Emergency Medical Services for low-energy defibrillation, transcutaneous pacing, cardioversion and monitoring.

TZ Medical 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.

TZ Medical 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.

TZ Medical 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.

TZ Medical Pediatric 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.

TZ Medical Multi-Function Defibrillation Electrodes are designed for single use with multiple defibrillators for biphasic defibrillation, pacing, monitoring, or cardioversion either directly or through adaptors.

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 Instructions for Use TZ Medical Defibrillator Pads.

V. **DEVICE DESCRIPTION**

The TZ Medical Multi-Function Defibrillation Electrodes and Adapters are designed for single use multiple defibrillators with biphasic defibrillation, pacing, monitoring, or cardioversion functionality either directly or through adapters.

The multi-function electrodes and adapters are used in clinical or medical facilities by trained personnel to allow monitoring, defibrillation, cardioversion and/or pacing without the need to apply multiple sets of electrodes.

TZ Medical defibrillation electrode pads are available in several different configurations as listed below in table (1). The part number describes how the pads are differentiated for adult and pediatric use, whether they are transparent or translucent, size of the pads and which connector is appropriate for each brand of defibrillator as demonstrated in tables (2 and 3).

Table 1: Defibrillator Electrode Pad Configurations/Part Number compatible with FDA approved Defibrillators

Product Description	Size	Universal ¹	Zoll ^{®2}	Medtronic ^{®3}
Adult Radiotransparent pads and leadwires	A	P-211-T1	P-211-Z1	P-211-M1
Adult Radiotransparent pads and leadwires, leads out	A	P-311-T1	P-311-Z1	P-311-M1
Adult Radiotransparent, large posterior pad	A/B	P-214-T1	P-214-Z1	P-214-M1
Adult Radiotranslucent, sterile	A	P-121-T1	P-121-Z1	P-121-T1*
Adult Radiotransparent pads and leadwires, large posterior pad, sterile	A/B	P-224-T1	P-224-Z1	P-224-T1*
Adult Radiotranslucent pads, leads out	A	P-111-T1	P-111-Z1	P-111-M1
Pediatric Radiotranslucent pads	C	P-112-T1	P-112-T1*	P-112-T1*
Pediatric Radiotranslucent pads, sterile	C	P-122-T1	P-122-Z1	P-122-T1*
Pediatric Radiotransparent pads and leadwires	C		P-212-Z1	P-212-M1

*Represented availability of adaptor cables with Anderson universal plug connectors, to connect with FDA approved defibrillators

Table 2: Part Number Definition

P	X	X	X
Defibrillator Pads	1 = Translucent	1 = Non-Sterile	Appropriate Plug Connector Z1 T1 M1
	2 = Transparent	2 = Sterile	
	3 = Leads out Transparent		

Table 3: Electrode Pad Sizes and Connectors

Electrode Pad Sizes	Defibrillator Connectors
A = 6.0" x 4.25" Standard B = 6.0" x 9.00" Large C = 4.25" x 2.876" Pediatric	1 = Zoll multifunction electrodes 2 = M1 Medtronic, Physio Control electrodes 3 = T1 Anderson model electrodes
A/A  B/A  C/C 	Z1 Connector  M1 Connector  T1 Connector 

TZ Medical Multi-Function Defibrillator Electrodes include an electrode, e.g., a thin metal conductor layer that rests on a foam backing. The electrode is covered with a conductive gel that contacts the patient's skin and electrically connects the electrode to the patient, and the electrode pad includes a ring of adhesive surrounding the conductive gel to adhere the electrode to the patient's skin. To prevent the adhesive gel from drying out and to maintain the electrodes sanitary or sterile condition and to cover the adhesive until ready to adhere the electrode to the patient, a release liner, e.g., bleached silicone paper is positioned over the adhesive and/or conductive gel of each electrode pad. TZ Medical provides two design variations of electrode pads utilizing slightly different components to achieve electrode pads that meet different clinical needs. Series P-1XX, table (4) are constructed to be translucent and Series P-2XX, table (5) are constructed be transparent. Both designs are applied in the same manner and are compatible with various makes and models of defibrillators. Both series are also provided in various sizes to meet the needs of pediatric and adult patients as noted in, table (3) and are identified by the third digit of the part number being a (2). A Large back electrode pad is available in both the transparent and translucent configuration as noted by the third number being a (4), see table 2.

Table 4: Radiopaque Electrodes (P-1XX Series)

Electrode Pad Components	Description
1	Apex base assembly: 1/32" 6# Polyethylene Foam with medical grade adhesive 2-3 mil. tin foil conductive plate Conductive adhesive hydrogel
2	Sternum base assembly (Same as line 1)
3	Insulating dot, 2mil white polyester with permanent adhesive
4	Eyelet, tin plated brass
5	Washer, tin plated brass
6	Connector, Option Appropriate connector plug: Z1,T1,M1 42"63" 65/36 18AWG Tinned copper wire
7	Front Pad Polyethylene Foam with medical grade adhesive
8	Rerelease liner, Bleached Kraft paper with silicone release coating

Figure 1: Radiopaque Electrode Diagram

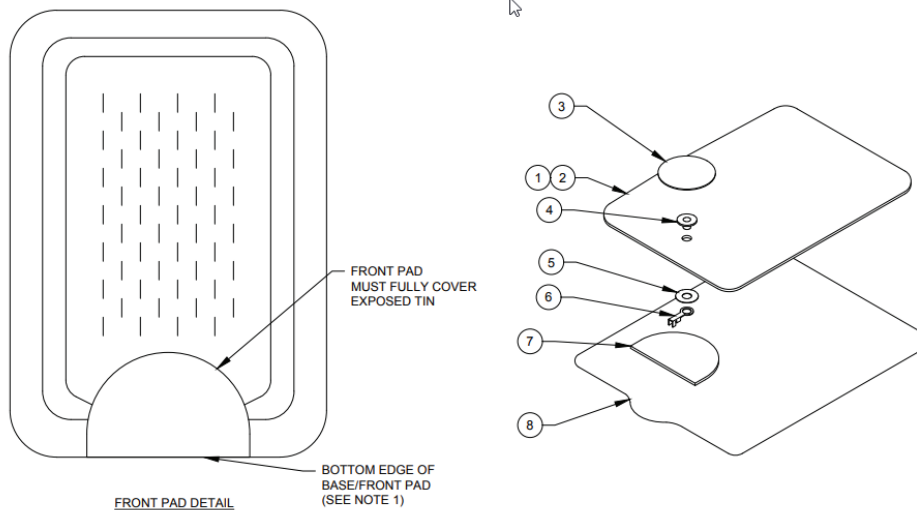


Table 5: Radiotranslucent Electrodes (P-2XX/3XX Series)

Electrode Pad Components	Description
1	Apex base assembly: Ag/AgCl coated carbon vinyl Conductive adhesive hydrogel Polyethylene Foam with medical grade adhesive
2	Sternum base assembly: (Same as line 1)
3	Aluminum Square
4	Connector, Option Appropriate connector plug: Z1,T1,M1 42"-63" Carbon lead wire
5	Front Pad Polyethylene Foam with medical grade adhesive
6	Release liner Bleached Kraft paper with Silicone release coating

Figure 2: Radiotranslucent Electrodes Diagram

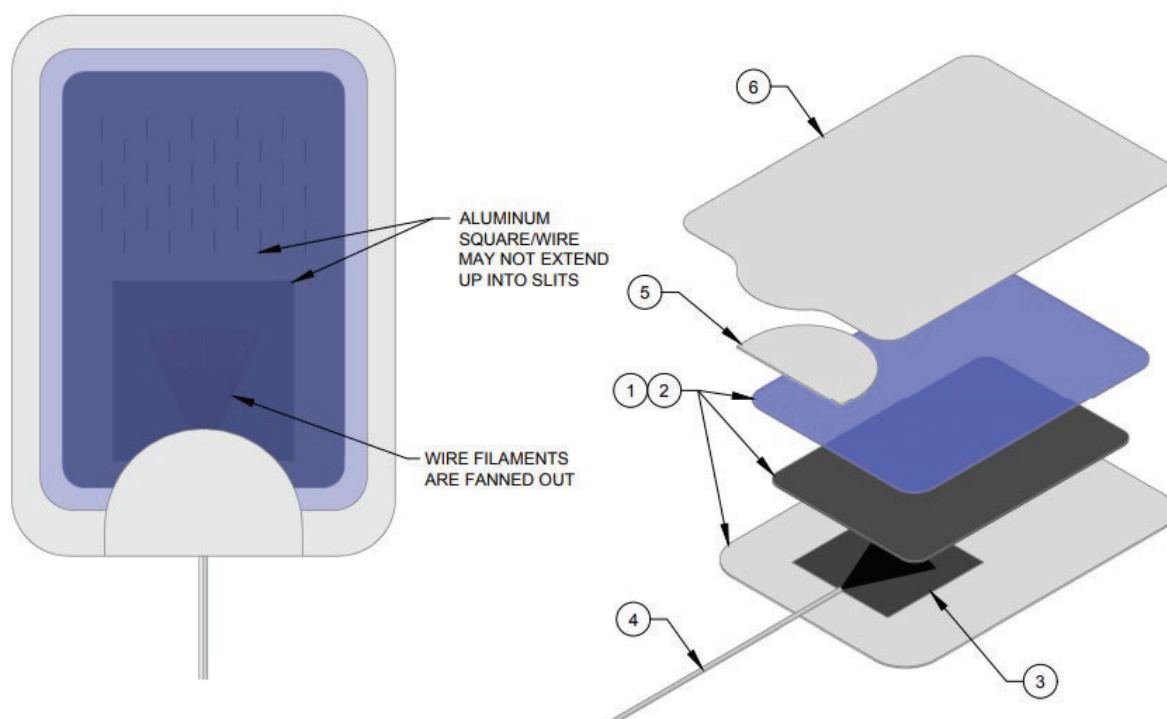


Table 6 – Adaptors

Part Number	Connections
PAD 101PD PAD 101PDL PAD 3020ZMI	Zoll Defibrillator to T1 Electrodes
PAD 1114	Zoll Defibrillator to M1 Electrodes
PAD 1111	Medtronic Defibrillator to T1 Electrodes
PAD 1113	Medtronic Defibrillators to Z1 Electrodes
PAD 3020QC	T1 Connector to Zoll Connector
PAD 1115	Z1 to Z1 extension cable
PAD 1110Z	PhysioControl Defibrillator to Z1 Electrodes
PAD 1115C PAD 1110	PhysioControl Defibrillator to T1 Electrodes

VI. **ALTERNATIVE PRACTICES AND PROCEDURES**

There are several other alternatives for the purpose of defibrillation, synchronized cardioversion, pacing, or electrocardiogram (ECG) monitoring. Each alternative has its own advantages and disadvantages.

- 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:

K983196: PADTAC Adult Defibrillation/Cardioversion/Pacing/Monitoring Electrodes

PadTac adult disposable electrodes are used by trained professionals in hospitals, doctor's offices, and Emergency Medical Services for pediatric low-energy defibrillation, transcutaneous pacing, cardioversion and monitoring.

K983232: PADTAC Pediatric Defibrillation/Cardioversion/Pacing/Monitoring Electrodes

PadTac Pediatric disposable electrodes are used by trained professionals in hospitals, doctor's offices, and Emergency Medical Services for pediatric low-energy defibrillation, transcutaneous pacing, cardioversion and monitoring.

PMA P200005 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 TZ Medical Multi-Function Defibrillation Electrodes are sold in the United States, Canada, South America and Asia Pacific.

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.

- Failure to identify shockable arrhythmia due to poor quality ECG signal.
- Failure to deliver a defibrillation shock in the presence of Ventricular Fibrillation (VF) or pulseless Ventricular Tachycardia (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.
- 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.

For the specific adverse events that occurred in the clinical study, please see Section X below.

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 6.

Table 7: Electrode Conformance Testing

Test Title	Results
Electrode Functional Testing (Electrical and Mechanical), Assembled Electrode, and Connectors	Pass
Defibrillator Compatibility Testing	Pass
EN 1041:2008 Information supplied by the manufacturer of medical devices	Pass
EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) EN ISO 10993-5:2009 Tests for invitro cytotoxicity EN ISO 10993-10:2010 Tests for irritation and skin sensitization	Pass
EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)	Pass
EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	Pass
EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)	Pass
EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Pass
EN 60601-2-4:2003 Medical electrical equipment -- Part 2-4: Particular requirements for the safety of cardiac defibrillators	Pass
EN 62366:2008 Medical devices - Application of usability engineering to medical devices	Pass

Bench testing comparing the original defibrillator system waveforms to the TZ Medical System (TZ Medical 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 TZ Medical 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 TZ Medical 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 TZ Medical System 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

TZ Medical 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.

TZ Medical 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 TZ Medical and OEM electrodes. By comparing the highest LSI electrode in the TZ Medical 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 TZ Medical line of products 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 TZ Medical 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.

TZ Medical'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 offered by TZ Medical.

Representative test sample electrode from each line of the TZ Medical system was selected and run in a side-by-side comparison to show equivalence to the OEM pad. Table 7 provides comparison between the TZ Medical electrode and OEM pad.

Table 8: TZ Medical Physio-Control Comparison Table

Physio Control Approved Pads	TZ Medical Equivalent PAD
LIFEPAK 15/20/20e/500/1000	
EDGE System Electrodes with QUIK-COMBO Connector and REDI-PAK™ Preconnect System 42 in. lead wire length 11996-000017	P-111 Family Electrodes PN: P111-T1, P111-Z1 P-311 Family Electrodes PN: P-311-M1,P-311-T1,P-311-Z1 P-211 Family Electrodes PN: P-211-K1, P-211-M1, P-211-P1, P-211-T1, P-211-Z1 P-214 Family Electrodes PN: P-214-M1, P-214-P1, P-214-T1,P-214-Z1 Sterile Electrodes: P-121 Family Electrodes PN: P-121-T1, P-121-Z1 P-224 Family Electrodes PN: P-224-T1, P-224-Z1
LIFEPAK 15/20/20e	
EDGE System Electrodes with QUIK-COMBO Connector 24 in. lead wire length 11996-000091	P-131 Family Electrodes PN: P131-T1, P131-Z1 P-311 Family Electrodes PN: P-311-M1,P-311-T1,P-311-Z1 P-211 Family Electrodes PN: P-211-K1, P-211-M1, P-211-P1, P-211-T1, P-211-Z1 P-214 Family Electrodes PN: P-214-M1, P-214-P1, P-214-T1,P-214-Z1 Sterile Electrodes: P-121 Family Electrodes PN: P-121-T1, P-121-Z1 P-224 Family Electrodes PN: P-224-T1, P-224-Z1

Pediatric EDGE System RTS Electrodes with QUIK-COMBO Connector For use only with manual monitor/defibrillators; 12 month minimum shelf life at time of shipment 24 in. lead wire length. 11996-000093	P-112 Family Electrodes - Pediatric PN: P-112-T1, P-112-Z1 P-212 Family Electrodes – Pediatric PN: P-212-M1, P-212-P1, P-212-T1, P-212-Z1 P-132 Family Electrodes – Pediatric PN: P132-Z1 Sterile Electrodes: P-122 Family Electrodes - Pediatric PN: P-122-T1, P-122-Z1
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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 R Series was chosen as the representative defibrillator for the ZOLL waveform tests.

Representative test sample electrode from each line of the TZ Medical system was selected and run in a side-by-side comparison to show equivalence to the OEM pad.

Table 8 provides comparison testing between ZOLL OEM equivalent electrodes and TZ Medical System.

Table 9: TZ Medical comparison to Zoll OEM Electrode

Zoll R, M, X Series	TZ Medical equivalent PAD
ZOLL Stat-padz PN: 8900-4004	P-111 Family Electrodes PN: P111-T1, P111-Z1
ZOLL Pro-padz PN: 8900-4055-40	P-311 Family Electrodes PN: P-311-M1,P-311-T1,P-311-Z1
	P-211 Family Electrodes PN: P-211-K1, P-211-M1, P-211-P1, P-211-T1, P-211-Z1
	P-214 Family Electrodes PN: P-214-M1, P-214-P1, P-214-T1, P-214-Z1

	Sterile Electrodes: P-121 Family Electrodes PN: P-121-T1, P-121-Z1 P-224 Family Electrodes PN: P-224-T1, P-224-Z1
Pedi-padz PN: 8900-3001-01	P-112 Family Electrodes - Pediatric PN: P-112-T1, P-112-Z1 P-212 Family Electrodes – Pediatric PN: P-212-M1, P-212-T1, P-212-Z1 P-132 Family Electrodes – Pediatric PN: P132-Z1 Sterile Electrodes: P-122 Family Electrodes - Pediatric PN: P-122-T1, P-122-Z1

Summary Results

Bench testing comparing the original defibrillator system waveforms to the TZ Medical system (TZ Medical 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 TZ Medical waveshapes were similar and that the difference between TZ Medical and OEM delivered energies were all within the pre-specified defibrillator energy accuracy as described in the respective OEM defibrillator Instructions for use.

Biocompatibility Testing

The electrodes were tested in accordance with ISO 10993 for cytotoxicity, irritation, and sensitization. TZ Medical biocompatibility testing was completed to ensure and show that patient contacting materials used in the pad are biocompatible. The non-patient contacting materials used in the pad do not leach through the patient contacting materials and do not pose a biocompatible risk to the patient.

Sterilization and Shelf-Life

The electrodes were sterilized by gamma radiation in accordance with ISO 11173 using VDmax25 and tested to the same standard as non-sterile electrodes.

The shelf life of the device is driven by the electrode material and the devices were tested using both real-time and high temperature accelerated aging procedures in compliance with IEC 60601-2-4:2010.

Real time and accelerated aging testing for the electrode supports a shelf life of 36 months.

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.

B. Animal Studies

Animal studies were not required to support approval of this PMA.

A single (Bovine) pig study was performed at John's Hopkins University School of Medicine in December 2005, by Dr. Henry Halparin, M.D. to evaluate and document the benefits of an improved gel design. Using a biphasic defibrillator from Medtronic a shock was delivered at 200 joules. A comparison was made between Kendal Medi Trace defibrillator electrode pads and TZ Medical defibrillator electrode pads. Thermal images were taken, within 1 second, of the area where the energy was applied. Following removal of the pads, within 1 minute, if burn marks were discovered images were recorded.

Results

Kendal Medi Trace™ defibrillator electrode pads exhibited a 17.7% higher temperature during shocks of 200 joules from a biphasic defibrillator and thus more likely to exhibit burns during maximum output from a biphasic defibrillator.

Conclusion

Under extreme operation and use, patients using TZ Medical defibrillator electrode pads are less likely to obtain burn marks when compared to patients using the Kendal Medi Trace™ defibrillator electrode pads.

C. Additional Studies

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

A Human Factors Risk Assessment was performed which included review of customer feedback, known risks, and publications of human factors testing with defibrillators. The TZ Medical Multi-Function Defibrillator Electrodes and Adaptors, when connected properly to a defibrillator, are intended to allow a trained user to monitor or detect the heart rhythm and deliver therapy. No residual human factor risks were identified in the development and risk analysis for the device.

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.

TZ Medical Electrodes are also monitored using the Post Market Surveillance and Clinical follow plan as required by Medical Device Directive (MDD), Medical Devices Regulation (MDR) and Medical Device Single Audit Program (MDSAP). Periodic

reviews are conducted throughout the year to ensure that identified risk are accurate and risk assessments have not changed.

X. SUMMARY OF PRIMARY CLINICAL STUDY

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. TZ Medical submitted a comparison of the original defibrillator system waveforms (Physio-Control and ZOLL) to the TZ Medical Multi-Function Defibrillation Electrodes with the same original equipment manufacturer (OEM) defibrillator waveforms. The waveform delivered by Physio-Control/Stryker, ZOLL, and TZ Medical 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 TZ Medical demonstrates that the adult and pediatric waveforms from TZ Medical 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^{1,2,3} for adult and pediatric uses of the TZ Medical Multi-Function Defibrillation Electrodes.

A. Published Clinical Data

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

Higgins et al.¹ 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.² A prospective, randomized 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, randomized 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 biphasic truncated exponential (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 TZ Medical Multi-Function Defibrillation Electrodes claiming compatibility to ZOLL defibrillators, the following study was leveraged:

Hess et. al.³, 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 TZ Medical demonstrates that the pediatric defibrillation waveforms from TZ Medical 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 TZ Medical 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.⁴ 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.

TZ Medical 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 had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

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 2009. For the TZ Medical Adult Multi-Function Defibrillation Electrodes, a total of 89 complaints were received between October 2009 to September 2018. The overall complaint rate was 0.0067%, and the reportable complaint rate to the FDA under the MDR system was 0.000% for the period of October 2009 to September 2018. For the TZ Medical Pediatric Multi-Function Defibrillation Electrodes, 0 complaints were received during this same timeframe.

Medical Device Reports: None issued by TZ

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 electrical energy, 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 TZ Medical Multi-Function Defibrillation Electrodes and Adaptors 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 TZ Medical 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 TZ Medical branded defibrillation electrodes (adult and pediatric) with the OEM defibrillator waveforms demonstrated that the waveforms were similar.

Additionally, a human factors assessment was also conducted to support the reasonable assurance of safety and effectiveness of the subject devices (refer to Section IX.B.).

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 TZ Medical Multi-Function Defibrillation Electrodes and Adaptors, for the stated indications for use.

Proactive and reactive surveillance is conducted on a quarterly basis by TZ Medical. Production, complaints, reports from field, and published literature are reviewed to assess the Risk associated with product and ensure continued compliance with

associated regulations. Changes to risk or associated products are immediately identified and steps to prevent safety concerns are produced and addressed.

C. Benefit-Risk Determination

TZ Medical Multi-Function Defibrillation Electrodes and Adaptors, 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 assessment, 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. TZ Medical continues to conduct post-market surveillance of the defibrillators to mitigate the risks of unknown compatibility issues for AEDs with whom TZ Medical does not have an agreement. Monitoring includes review of the FDA's MAUDE Database, PMA Approval Database, Literature Databases.

1. Patient Perspective

This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the available information above, the probable benefits outweigh the probable risks for the TZ Medical Multi-Function Defibrillation Electrodes and Adaptors, 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 1/09/2024.

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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3. Hess EP, Agarwal D, Myers LA, et. al., Performance of a rectilinear biphasic waveform in defibrillation of presenting and recurrent ventricular fibrillation: a prospective multicenter study. Resuscitation. 2011;82(6):685-9.

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