SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Multipurpose Defibrillator Pads (Manual or Automated External Defibrillator Pad)

Device Trade Name: HeartSync Multifunction Disposable Single-Use AED Defibrillator Pads

Device Procode: MKJ

Applicant's Name and Address: Graphic Controls dba Nissha Medical Technologies/ Vermed/ Biomedical Innovations
400 Exchange Street, Buffalo, NY 14204

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P200007

Date of FDA Notice of Approval: 6/23/2023

II. INDICATIONS FOR USE

These are multifunction pads, and can be used with automatic or manual defibrillators for monitoring, pacing, cardioversion, as well as defibrillation. These indications are consistent with current AHA Guidelines.

For Automatic External Defibrillators:
(Compatible Model AEDs: Physio Control: LifePak-15, LifePak-20/20e, LifePak -1000; Zoll Medical: R-Series, X-Series; Cardiac Science: PowerHeart AED G3 Plus, PowerHeart AED G3 Pro).

When used with an external defibrillator, these electrode pads are for treating patients in cardiopulmonary arrest who are:

- Unconscious,
- Not breathing spontaneously
- Without circulation (without a pulse).

The pads are single use and intended to be used in conjunction with an external defibrillator to monitor and deliver defibrillation energy to the patient. The pads are used

on patients over 8 years of age or greater than 55 pounds. The pads are intended for short term use (less than 8 hours).
DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.

For Manual Defibrillators:
Manual Defibrillators can be used for monitoring, pacing, cardioversion, as well as defibrillation.

When used for defibrillation, these electrode pads are for treating patients in cardiopulmonary arrest who are:

- Unconscious,
- Not breathing spontaneously
- Without circulation (without a pulse).

The pads are single use and intended to be used in conjunction with an external defibrillator to monitor and deliver defibrillation energy to the patient. The pads are used on patients greater than 10 kg or 22 pounds. The pads are intended for short term use (less than 24 hours).
DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.

III. CONTRAINDICATIONS

Contraindications for use should be followed as per the compatible AED/ defibrillation unit.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the HeartSync Defibrillation Electrodes labeling.

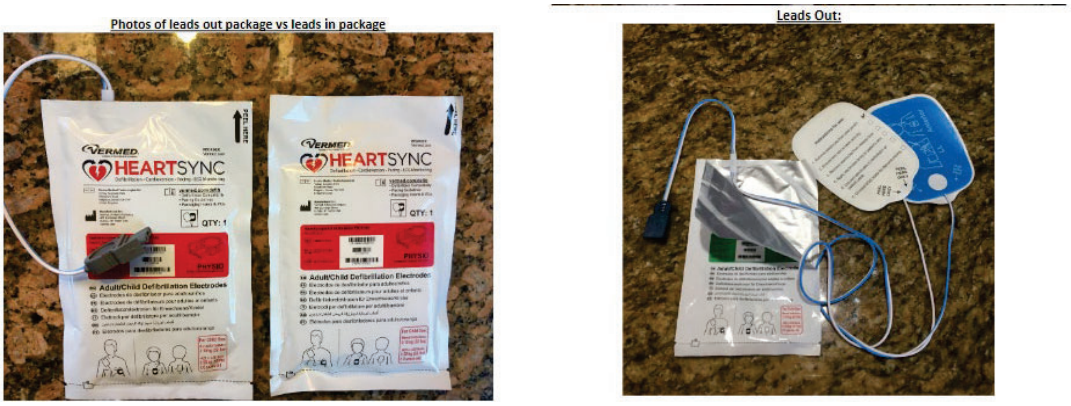
V. DEVICE DESCRIPTION

The HeartSync electrodes are intended to be used in external pacing, cardioversion, defibrillation, and monitoring applications as a non-sterile, disposable device for single patient use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patient's skin. When a patient requires defibrillation, cardioversion or external pacing, these electrodes will be applied to the patient and connected to the instrument. The pads are packaged in airtight pouches either with the leads inside the package or leads outside the package. The package is designed to keep the pads clean and prevent them from drying out. See Figure 1 below.

These are single use, non-sterile, self-stick defibrillator electrodes packaged in pairs. The effective electrode area is 207.6 cm2. They are packaged with a connector to match the

specific defibrillator. The patient contact material is a conductive adhesive hydrogel. Each electrode consists of foam backing, conductor plate (either tin or carbon), layer of electrically conductive and adhesive hydrogel, protective release liner, insulated wire connected to the conductor plate, and a connector specific to the defibrillator manufacturer.

Figure 1



See Table 1 below for a list of HeartSync Defibrillation Models and the compatible devices.

Table 1

OEM	Defibrillators	HeartSync Models
Physio Control	LifePak-15 LifePak- 20/20e LifePak-1000	T100AC-Physio T100LOAC-Physio C100AC-Physio C100LOAC-Physio
Zoll Medical	R-Series X-Series	T100AC-Zoll T100LOAC-Zoll T100AC-Zoll-10 C100LOAC-Zoll C100AC-Zoll
Cardiac Science	PowerHeart AED G3 Plus PowerHeart AED G3 Pro	T100-CS

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of external pacing, defibrillation, and monitoring. Alternative products (including those marketed by the AED device

original equipment manufacturer can be utilized. Traditional CPR can be considered in the absence of an AED. Each alternative has its own advantages and disadvantages.

VII. MARKETING HISTORY

The HeartSync Defibrillation Electrodes have been marketed in the United States as seen in Table 2 below.

Table 2 510(k) References

Device Name	Applicant	510(K) Number	Decision Date
Heart Sync	Heart Sync, Inc	K131550	12/06/2013
Heart Sync	Heart Sync, Inc	K131494	09/16/2013
Heart Sync pediatric Physio AED Pad	Heart Sync, Inc	K20536	08/06/2012
Heart Sync Pediatric, Model Ped-100	Heart Sync, Inc	K081442	09/24/2008
Heart Sync, Models C-100 and T-100	Heart Sync, Inc	K080421	02/29/2008

HeartSync Defibrillation Electrodes are marketed in Europe, Canada, Middle East, Latin America and the United States and have not been withdrawn from any market due to concerns regarding safety or effectiveness.

Single use defibrillator pads have been in distribution since 1994 and have been the subject of numerous 510(k) submissions. As a result of FDA Final Order [Docket no. FDA-2013-N-0234], single use defibrillator pads (accessories) for AED use are now required to have premarket approval under product code MKJ as a Class III device. Prior to Feb 3, 2015, defibrillator pads were marketed as Class II devices requiring a 510(k). HeartSync previously submitted and marketed single use defibrillator pads under the 510(k)s described above.

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.

- There is a risk of failure to defibrillate a patient in cardiac arrest if the connections to the pad fail.
- There is a risk of electrical shock to the person administering the AED therapy.
- There is a risk of burn to the patient at the electrode site if the skin-pad resistance is high.
- There is a slight risk of skin irritation at the electrode site, mitigated by biocompatibility testing.

IX. SUMMARY OF NONCLINICAL STUDIES

A. Laboratory Studies

Table 3

Test	Objective	Standard/Acceptance	Results
Biocompatibility	To determine acceptable use on patient skin through cytotoxicity studies, sensitization studies, and skin irritation studies per ISO standard. Patient Contacting Materials: Hydrogel, Foam Adhesives and Foam. Cytotoxicity: Hydrogel – Direct Contact Cytotoxicity: Foam and Foam Adhesives – ISO Agarose Overlay Method. Sensitization: Closed Patch Sensitization Study in Guinea Pigs Skin Irritation: ISO Skin Irritation Study in Rabbits	ISO 10993-1, ISO 10993-5, and ISO 10993-10	Pass
Packaging			
Shelf Life	To verify established shelf life and function. Samples were both real-time aged and aged using accelerated methods to 3.5 years then subjected to Bubble Emissions, Pouch Seal Strength, and Visual Inspection.	ASTM F1980 ASTM F1886-08R13 Must meet criteria for each post-test after aging.	Shelf Life

Test	Objective	Standard/Acceptance	Results
Pouch Integrity: Bubble Emissions	To determine pouch ability to maintain hydrogel moisture and pressure within pouch. Uses externally applied pressure to detect escaping air.	ASTM F2096-11 Must not have steady stream of bubbles.	Pouch Integrity: Bubble Emissions
Pouch Integrity: Pressure Decay	To determine pouch ability to maintain hydrogel moisture and pressure within pouch. Uses internally applied pressure (13.8 in H2O) and is measured after 60s.	Pressure must be greater than 7.0in H2O.	Pouch Integrity: Pressure Decay
Pouch Seal Strength	To determine pouch ability to maintain hydrogel moisture and pressure within pouch. Pulls two sides of pouch away from each other at 10in/min at 180° angle (ASTM Technique C).	ASTM F088-09 Peel is 1.0lbf/min or greater	Pass
Transit Test	To ensure pouches maintain seal and internal integrity after shipping and handling. Samples are pre-conditioned then subjected to Distribution cycle for Handling, Vehicle Stacking, Loose-Load Vibration, Low Pressure, Vehicle Vibration, Concentrated Impact, and Second Handling tests. Samples are then tested for Bubble Emissions, Pouch Seal Strength, and Visual Inspection.	ASTM D4169-16 ASTM D4332-14 ASTM F1886-08R13 Must meet criteria for each sub-test after aging.	Pass
Storage Test	To ensure pouches and hydrogel maintain properties after storage at temperature extremes. After storage at extreme low temperature, tested for Bubble Emissions, Pouch Seal Strength, and Visual Inspection.	ASTM D4332-14 ASTM F1886-08R13 Must meet criteria for each sub-test after aging.	Pass

Test	Objective	Standard/Acceptance	Results
Mechanical			
Adhesion Peel Strength	To verify the hydrogel adheres to the patient. Samples are pulled at a rate of 12in/min at a 90° angle to a sliding stainless-steel plate while the force is measured.	ASTM D6252 Average peak force shall be greater than 0.5ozf/min	Pass
Wearability	To verify that electrodes remain adhered to the patient for up to 24 hours. Samples are adhered to skin of participants for over 24 hours.	AAMI EC12-2000+(R2020) Samples are still adhered after 24 hours	Pass
Connector Compatibility	To ensure the connector properly connects to the generator and transmits energy. Perform measurements against drawings and perform tolerance analysis with Root Sum Squared compared with the mating connector.	Measurements do not preclude connector from functioning to retain receptacle and electrical contact.	Pass
Cable Anchorage	To ensure cable can withstand loading off-axis without loss of function. Electrode and connector tested at termination of cable. The connection material is oscillated with a 5N load applied at angles of 45° and 90° and a rate of 30 cycles/min. Samples are then subjected to Electrical Performance tests.	ANSI/AAMI/IEC 60601-2-4:2010/A1:2018 Cable has not worked loose and passes post-test acceptance criteria.	Pass
First Article Inspections	To ensure materials meet design specifications for size and manufacturer testing processes. Compare specifications to material.	Acceptance per each component's specifications.	Pass

Test	Objective	Standard/Acceptance	Results
Electrode Area	To ensure an area large enough to disperse energy without burning the patient. Measure dimensions of the effective area of the electrode to calculate the area.	ANSI/AAMI/IEC 60601-2-4:2010/A1:2018 Area of each individual electrode shall be greater than 50cm^2 and the sum of the pair shall be greater than 150cm^2.	Pass
Electrical			
Oscilloscope Waveform Testing	To compare the waveform parameters with the waveform of the OEM electrodes. Electrodes are shocked at energies with a range of impedance from 25Ω to 200Ω (when applicable) at maximum energy or highest energy protocol and at lowest energy or energy protocol.	AAMI TIR62 Energy must be within 15%, or 3J of the OEM, whichever is greater. All other parameters were nearly identical to the OEM and met predetermined acceptance criteria.	Pass
Surface & Volume Resistivity	To ensure sufficient resistivity to disperse the energy across the effective area of the electrode. Resistive measurements taken on a sample of gel material.	Resistivity must be within ±5% of the published value for the gel resistivity.	Pass
Electrical Performance: Defibrillator Recovery	To ensure adequate energy dispersion in a timely manner. Potential measured across electrodes at 4s and 60s after shock and performed before and after pacing for 60min.	ANSI/AAMI/IEC 60601-2-4:2010/A1:2018 Potential shall not exceed the following: 4s Pre-Pace: 500mV 60s Pre-Pace: 400mV 4s Post-Pace: 1000mV 60s Post-Pace: 750mV	Pass

Test	Objective	Standard/Acceptance	Results
Electrical Performance: Direct Current Offset	Offset voltage to ensure proper baselining of measurement equipment. Measured across electrodes after 1 min stabilization through a 10MΩ resistor.	ANSI/AAMI/IEC 60601-2-4:2010/A1:2018 Offset Voltage shall not exceed 100mV.	Pass
Electrical Performance: Alternating Current Signal Impedances (Small 10Hz & 30kHz and Large)	To ensure proper measurement of impedance of the patient for determination of shock delivery energy. Using frequencies of 10Hz and 30kHz, impressed current of 100µA measured peak-to-peak across electrode pair (AC Small), measures the impedance. Test is repeated with 50Ω load and measured at 360J of Defibrillator shock (AC Large). All tests are repeated after 60min of pacing.	ANSI/AAMI/IEC 60601-2-4:2010/A1:2018 AC Small 10Hz: 3000Ω AC Small 30kHz: 10Ω AC Large: 5Ω	Pass
Energy Discharge Verification	To ensure electrodes can withstand 50 defibrillation shocks. Total energy of the shock is measured over 50 repeated shocks at maximum energy of the defibrillator.	Total energy shall not decrease by more than 10% of the 3rd shock on any of the 50 shocks.	Pass
Pacing Confirmation	To ensure electrodes can perform per published pacing charts. At both 20ms and 40ms pulse widths, samples were tested at various parameters per the HeartSync Pacing Guidance charts, then subjected to three (3) defibrillation shocks at maximum energy.	The 95%/90% Confidence/Population of the lower limit on total energy delivered across all shocks shall not be below -10% of the selected energy for each of the configurations (Conductor and Pulse Width).	Pass

Test	Objective	Standard/Acceptance	Results
Dielectric Strength Testing	To ensure cable can withstand high-voltage shocks and protect the user. Perform Hi-Pot test on samples of all connector lead types.	ANSI/AAMI/IEC 60601-2-4:2010/A1:2018 Leakage current shall be less than 15 μA.	Pass

B. Animal Studies

There were no animal studies conducted.

C. Additional Studies

Table 4

Test	Objective	Standard/Acceptance	Results
Labeling			
GHTF Label and Instructions for Use	To ensure compliance to GHTF/SG1/N70:2011 Compare GHTF requirements against labels and IFU	GHTF/SG1/N70:2011 ISO 15223-1:2021 All labels and IFUs must meet standard	Pass
FDA Device Labeling 120	To ensure compliance to 21 CFR 820.120. Compare CFR requirements against labels and IFU	21 CFR 820.120 All labels and IFUs must meet standard	Pass
Part 801 Labeling	To ensure compliance to Subpart A Compare Subpart A requirements against labels and IFU	Sec 801.15 All labels and IFUs must meet Subpart A 801.15	Pass
Labeling Verification	To ensure labeling meets Product Specifications Compare labeling requirements within the Product Specification to IFUs and product labels	All product labeling specifications must be met	Pass

Test	Objective	Standard/Acceptance	Results
Human Factors			
Summative Usability Study	To assess labeling and Instructions for Use (IFU) effectiveness in a simulated clinical environment. Evaluate users as they perform use case scenarios of HeartSync electrodes. Participants' ability to properly use the device was evaluated against the intended use.	ANSI/AAMI/IEC 62366:2007/(R) 2013 ANSI/AAMI HE75:2009/(R) 2018 FDA – Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff, Feb 3, 2016 Each participant's accuracy and overall study accuracy must meet minimum percentage per protocol.	Pass
Human Factors Comparative Study	To ensure human factors of the use of HeartSync devices do not introduce any additional mis-use risk when compared to the OEM device. Comparison of IFU for OEM to HeartSync.	Comparative risk assessment shows no increased risk with HeartSync devices	Pass

X. SUMMARY OF PRIMARY CLINICAL STUDY

As per FDA Final Order, "Effective Date of Requirement for Premarket Approval for Automated External Defibrillator Systems," published February 3, 2015, existing published clinical literature may be leveraged as part of the PMA submission. Published clinical studies, performance testing, and post market surveillance data were utilized to support the clinical application of the subject devices.

A. Study Design

Oscilloscope Waveform Testing was completed to compare the waveform parameters of HeartSync Defibrillation Electrodes with the waveform of the OEM electrodes. Defibrillation shocks were applied through the electrodes with a range of impedance from 25Ω to 200Ω (when applicable) at maximum energy or highest energy protocol and at lowest energy or energy protocol. Energy was found to be within 15%, or 3J of the OEM, whichever is greater.

All other parameters (listed below) were nearly identical to the OEM and met predetermined acceptance criteria.

- Peak current of the leading edge of the first and second phase
- Peak voltage of the leading edge of the first and second phase
- First and second phase duration
- First and second phase tilt
- Selected energy and delivered energy

Nissha Medical performed an oscilloscope waveform comparison study, where the peak voltage, peak current, phase duration, and tilt were evaluated for both phases of the biphasic waveform as well as total energy delivered. The data generated for this study proved that the HeartSync electrodes performed the same as the OEM electrodes, thus indicating the same therapy is being delivered to the patient. The output waveforms were evaluated for clinical relevance in the respective SSED of the defibrillator as detailed by each manufacturer below.

B. Safety and Effectiveness Results

PUBLISHED CLINICAL DATA

The results of the Physio-Control OEM electrode to HeartSync comparisons demonstrated a comparable performance to the OEM electrodes. Therefore, as the Physio-Control electrodes have been approved by the FDA and considering[1] the clinical evaluation in the van Alem's 2003 study[2], the HeartSync electrodes for Physio-Control defibrillators can be inferred to be as effective as the OEM Physio-Control electrodes for electrophysiological treatments using the Physio-Control biphasic truncated exponential waveform.

The results of the Cardiac Science OEM electrode to HeartSync comparison demonstrated a comparable performance to the OEM electrodes. Therefore, as the OEM Cardiac Science electrodes have been demonstrated as clinically relevant[3,4] with the clinical evaluation referenced in Kerber's 1997 study[5], the HeartSync electrodes for Cardiac Science defibrillators can be inferred to be as effective as the OEM Cardiac Science electrodes for electrophysiological treatments using the Cardiac Science STAR® biphasic waveform.

The results of the Zoll OEM electrode to HeartSync comparison demonstrated a comparable performance to the OEM electrodes. Therefore, as the OEM Zoll electrodes have been demonstrated as clinically relevant[6] with the clinical evaluation referenced in Hess's 2012 study[7], the HeartSync electrodes for Zoll defibrillators can be inferred to be as effective as the OEM Zoll electrodes for electrophysiological treatments using the Zoll rectilinear biphasic waveform.

ELECTRICAL TEST RESULTS

In addition to the Oscilloscope Waveform analysis identified above that was conducted using the HeartSync electrodes as compared to OEM electrodes, and the supporting clinical data provided for the OEM electrodes; the HeartSync product was evaluated against the current international standard: ANSI/AAMI/IEC 60601-2-4:2010/A1:2018 for electrical performance testing in order to demonstrate safety and effectiveness:

1. Surface & Volume Resistivity testing was conducted to ensure sufficient resistivity to disperse the energy across the effective area of the electrode.
2. Defibrillator Recovery testing was conducted to ensure adequate energy dispersion in a timely manner.
3. Direct Current Offset testing was performed to ensure proper baselining of measurement equipment.
4. Alternating Current Signal Impedance test ensuring proper measurement of impedance of the patient for determination of shock delivery energy.
5. Energy Discharge Verification testing was conducted to ensure electrodes can withstand 50 defibrillation shocks.
6. Pacing Confirmation testing ensures electrodes can perform per published pacing charts.
7. Dielectric Strength Testing was conducted to ensure cable can withstand high-voltage shocks and protect the user.

HUMAN FACTORS TEST RESULTS

The safe and effective use of the HeartSync product was demonstrated with the successful completion of the following human factor studies:

1. Summative Usability Study, used to assess labeling and Instructions for Use (IFU) in a simulated clinical environment. Users were evaluated as they performed use case scenarios of HeartSync electrodes. Participants' ability to properly use the device was evaluated against the intended use.
2. Human Factors Comparative Study, conducted to ensure human factors of the HeartSync devices do not introduce any additional mis-use risk when compared to the OEM device.

1. Pediatric Extrapolation

   In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

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

Since the Acquisition of HeartSync by Graphic Controls in May 2018 and through June 2023, there have been a total of 61 complaints related to product quality for HeartSync Defibrillation Electrodes. These complaints were evaluated and compared to the total amount of units sold in this period. The evaluation determined that the HeartSync Defibrillation Electrodes product family yielded a complaint rate of only .0013%. In addition, these complaints were reviewed regarding adverse event reporting. This review concluded that the complaint rate for reportable events was 0.0003%.

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

The outcomes of the Nonclinical Studies (Performance Testing) have demonstrated that the HeartSync Defibrillation Electrodes waveform delivery is comparable to the OEM defibrillation pads and have proven via design verification the reasonable effectiveness of the device. This includes the applicable specifications outlined in IEC 60601-2-4:2010/A1 :2018.

Conclusions of the Design Verification related to wearability of the device demonstrated that HeartSync Defibrillation Electrodes remain adhered to the patient for 24 hours after application. Additionally, the Human Factors Assessment performed compared the usability of HeartSync Defibrillation Electrodes to the OEM counterparts, and found that in all cases, the information on how to use the HeartSync device is both pictorially clear and the instruction as complete as the OEM devices.

Since the Acquisition of HeartSync by Graphic Controls in May 2018 and through June 2023, there have been a total of 61 complaints related to product quality for HeartSync Defibrillation Electrodes. This represents a complaint rate of .0013%.

B. Safety Conclusions

The risks of the device are based on Nonclinical Studies (Performance Testing), existing clinical data, design verification, and post market surveillance conducted to support PMA approval as described above. Due to the longstanding commercial use of the HeartSync product line, the results of performance testing, and the low complaint rate and adverse event rate the risks and safety of the device have been found to be appropriately mitigated.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. HeartSync Defibrillation Electrodes were originally reviewed and FDA-cleared via FDA 510(k) notifications and have been commercially available since 2008.

The established benefits and risks of the electrodes have been evaluated using post market surveillance information, existing clinical data, and design verification/performance testing.

The HeartSync Defibrillation Electrodes are accessories to AEDs. The benefit of AED use is increased chance of survival in a cardiac arrest by acutely treating ventricular fibrillation and pulseless ventricular tachycardia. Defibrillation in emergency events is life- saving and the ability to deliver defibrillation therapy quickly is imperative.

The probable risks of the device are also based on post market surveillance information and existing clinical data. The benefits of defibrillation to sustain life far outweigh the risks associated with it.

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 data supports that for external pacing, cardioversion, defibrillation, and monitoring applications the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. For patients in cardiopulmonary arrest who are unconscious, not breathing spontaneously, or without circulation (without a pulse), or in need of external pacing, cardioversion, or monitoring, the benefits of HeartSync Defibrillation Electrodes outweigh the risks.

XIV. CDRH DECISION

CDRH issued an approval order on 6/23/2023.

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

1. Physio-Control LIKEPAK FDA Summary of Safety and Effectiveness Data (SSED), PMA P160026

2. van Alem AP, Sanou BT, Koster RW. Interruption of cardiopulmonary resuscitation with the use of the automated external defibrillator in out-of-hospital cardiac arrest. Ann Emerg Med. 2003 Oct;42(4):449-57. doi: 10.1067/s0196-0644(03)00383-4. PMID: 14520315. https://doi.org/10.1016/S0300-9572(03)00216-8

3. Zoll Medical Corporation FDA Summary of Safety and Effectiveness Data (SSED), PMA P160033

4. Zoll Medical Corporation FDA Summary of Safety and Effectiveness Data (SSED), PMA P160034

5. RE Kerber, et al. "Automated External PMA P160034: FDA Summary of Safety and Effectiveness Data Page 16 Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm

Performance, Incorporation New Waveforms, and Enhancing Safety." Circulation (1997), Vol 95, No 6, 1677-1681. https://www.ahajournals.org/doi/10.1161/01.CIR.95.6.1677

6. ZOLL Medical Corporation FDA Summary of Safety and Effectiveness Data (SSED), PMA P160022

7. Hess EP, White RD. Automated external defibrillation. Crit Care Clin. 2012 Apr;28(2):143-53. doi: 10.1016/j.ccc.2011.10.009. Epub 2011 Dec 1. PMID: 22433479. https://doi.org/10.1016/j.ccc.2011.10.009