SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Wearable Cardioverter Defibrillator

Device Trade Name: LifeVest® Wearable Cardioverter Defibrillator

Device Procode: MVK

Applicant's Name and Address: ZOLL Manufacturing Corporation
121 Gamma Dr.
Pittsburgh, PA 15238

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P010030/S056

Date of FDA Notice of Approval: December 17, 2015

The Original PMA (P010030) was approved on December 18, 2001 and is indicated for the treatment of adult patients who are at risk of sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator. The SSED to support the indication is available on the CDRH website: http://www.accessdata.fda.gov/cdrh_docs/pdf/P010030b.pdf. The current supplement was submitted to expand the indication for the LifeVest® Wearable Defibrillator to include the treatment of life-threatening arrhythmias in pediatric patients with a chest circumference of 26 inches and a weight of 18.75kg (average size of an 8 year old) or greater who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator. No modifications to the currently approved LifeVest® devices are proposed for their use with pediatric patients.

II. INDICATIONS FOR USE

The LifeVest® system is indicated for patients 18 years of age and older who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator.

The LifeVest® system is indicated for patients under 18 years of age who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator. Patients must have a chest circumference of 26 inches (66 centimeters) or greater and a weight of 18.75 kilograms (41.3 pounds) or greater.

III. CONTRAINDICATIONS

The LifeVest® system is contraindicated for use in patients with an active implantable defibrillator.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the LifeVest® Models 3000, 3100, and 4000 labeling.

V. DEVICE DESCRIPTION

This supplement requests approval of three (3) commercially available models of the LifeVest® device (3000, 3100, and 4000) for use in pediatric patients who meet the size requirements for the device and are at risk for sudden cardiac arrest. There have been no modifications to the LifeVest® devices for use with pediatric patients.

The LifeVest® is a Wearable Cardioverter Defibrillator (WCD) worn by patients at risk of sudden cardiac arrest (SCA). It monitors the pediatric patient's heart continuously by using four (4) dry electrocardiogram (ECG) electrodes. If the patient goes into a life-threatening Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF,) the LifeVest® is able to deliver a treatment shock to restore the patient's heart to normal sinus rhythm. The LifeVest® system consists of two (2) main components, a Monitor and an Electrode Belt. The Monitor is the main unit of the LifeVest® system. It connects to the Electrode Belt, analyzes the patient's ECG, and delivers a therapeutic shock when required. The Electrode Belt consists of four (4) ECG monitoring electrodes and Therapy Electrodes which dispense Blue™ gel and deliver the cardioverting/defibrillating energy through the patient's chest when the patient experiences a life-threatening VT or VF.

When the device detects a treatable arrhythmia, an alarm sequence begins, giving a conscious patient time to stop the treatment. If the patient holds the two (2) response buttons on the Monitor at any time during the treatment sequence, the alarms stop and no treatment shock will be delivered. If the patient does not respond or releases the response buttons, the device continues to give alarms and verbal warnings to bystanders that a treatment shock is about to be delivered. If the arrhythmia continues after the first shock, up to five (5) shocks may be given in a treatment sequence.

The LifeVest® is a prescription device, where the patient's physician sets the VT/VF rate thresholds and pulse energy level for the patient. The rate threshold is the heart rate that must be sustained before VT or VF is declared. The pulse energy is the energy level (in joules) of each of the five (5) shocks, which can range from 75J to 150J. The algorithm uses the patient's baseline vectorcardiogram as a template for detecting changes in cardiac signal morphology, in addition to standard rate determination of arrhythmias.

The patient's ECG is recorded for all detected arrhythmias, including before and after treatment. The patient can also manually record an ECG at any time by pressing the response buttons on the device. Data stored within the LifeVest® is periodically uploaded to a secure internet website, LifeVest® Network (LVN), for subsequent physician review. Data transmission to LVN is encrypted for security reasons. Access to LVN is restricted to authorized users via user names and passwords.

The most recent LifeVest® model (4000) is described in detail below. The other two (2) models of the LifeVest® that are currently marketed (3000 and 3100) have essentially the same components and mechanism of action as the 4000 and differ with respect to minor design upgrades. The difference between the 3000 and 3100 models is that the alarm module in the 3100 model is integrated into its monitor while the 3000 has a separate alarm modules that connects to its monitor.

Figure 1 illustrates the various physical components of the LifeVest® 4000 system. Tables 1 and 2 list the various components of the LifeVest® and provide a detailed description for each component.

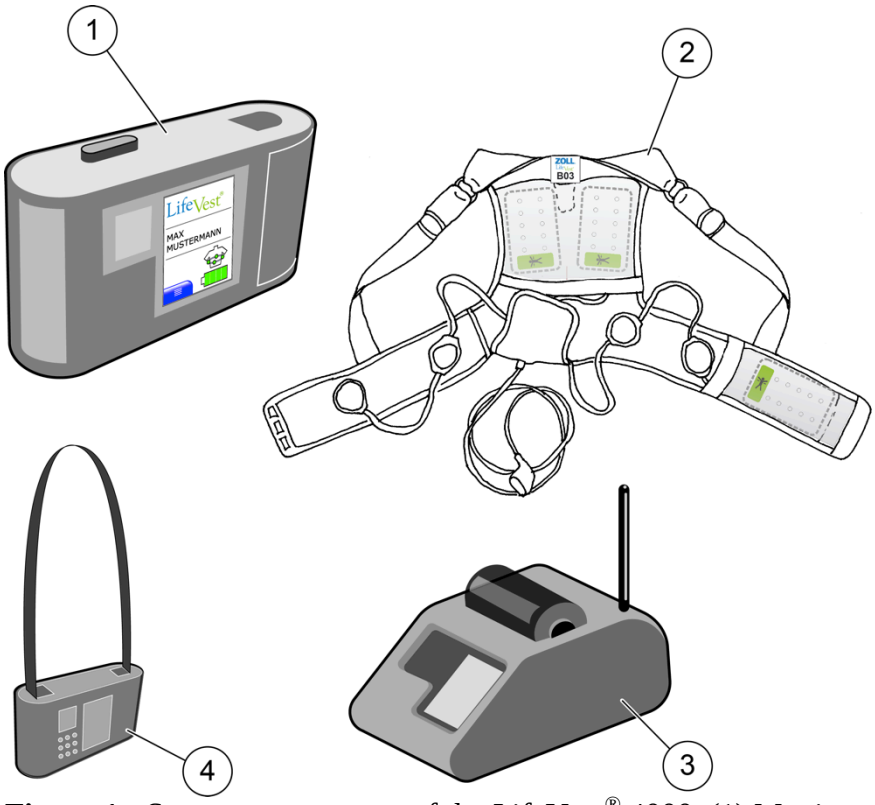

Figure 1: System components of the LifeVest® 4000, (1) Monitor, (2) Electrode Belt attached to Garment, (3) Battery Pack in Battery charger/Modem, (4) Monitor in Holster

Table 1: LifeVest® 4000 System Wearable Components

LifeVest® 4000 Device Wearable Component	**Description**
Monitor	This is the main unit of the LifeVest® system. It connects to the Electrode Belt and analyzes the pediatric patient's ECG and delivers a therapeutic shock when required. The monitor contains the diagnostic circuitry and the shock circuitry. A color touchscreen display allows the patient to access help screens regarding alarms and daily functions of the device.
Battery Pack	The Battery Pack is a rechargeable power source that attaches to the monitor and when depleted, the patient removes it and replaces it with a second fully-charged Battery Pack. Patients are instructed to replace the Battery Pack daily.
Electrode Belt	The Electrode Belt connects to the Monitor. The Electrode Belt consists of the dry ECG monitoring electrodes and the therapy electrodes, all interconnected by electrical wiring. Four (4) ECG monitoring electrodes are designed to provide continuous body-surface ECG monitoring. Three (3) Therapy Electrodes are designed to deliver the cardioverting/defibrillating energy through the patient's chest. The Therapy Electrodes dispense Blue™ gel if a defibrillating shock is needed.
Garment	The garment with attached Electrode Belt fits around the patient's chest. The garment holds the ECG and Therapy Electrodes in proper position and is worn under the patient's clothing, next to the skin.
Holster	The Holster provides a convenient method of carrying the Monitor.

Table 2: LifeVest® 4000 System Non-Wearable Components

Non-wearable Component	Description
Battery Charger/ Modem	The Battery Charger/Modem recharges the spare Battery Pack while the monitor is being worn. It also acts as a modem or wireless gateway to securely transmit data periodically for doctor review either by cellular connection or standard phone line.
LifeVest® Network	A secure ZOLL maintained website that collects patient information and forms a patient history of ECG recordings and other data. Physicians can securely access their patient's information from virtually any computer with internet access. LifeVest® Network allows physicians to view ECG recordings, patient use, and other device-related information.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of life-threatening arrhythmias in pediatric patients who are at risk for sudden cardiac arrest. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

- *Emergency Medical Services (EMS) or Calling 911*. Paramedics are trained to diagnose countershock or defibrillation-reversible conditions and apply such therapy if needed.

- *Automatic External Defibrillators (AEDs) in the Community*. AEDs are increasingly being deployed in a large number of settings by minimally trained "first responders," such as police, firemen, security guards, and others.

- *Automatic External Defibrillators (AEDs) in the Home*. AEDs may be prescribed for use within the home.

- *Implantable Cardioverter Defibrillators (ICDs).* ICDs are surgically implanted in patients shown to have long-term (permanent) risk of SCA to protect them from sudden cardiac death. In general, patients having uncertain or temporary SCA risk are not indicated for ICD implantation.

- *Antiarrhythmic Medication*. Some drugs such as amiodarone and beta-blockers have been shown to decrease the number of ventricular arrhythmias and thus reduce the incidence of SCA. However, they are limited in use to patients who have already experienced ventricular tachyarrhythmias.

- *Telemetry Monitoring within a Hospital Environment*. Within the hospital environment, telemetry maybe used to monitor for arrhythmias and treat them with rapid defibrillation. This approach requires hospitalization.

VII. MARKETING HISTORY

The marketed LifeVest® Models 3000, 3100, and 4000, (P010030/S003, S007, and S011, respectively) have been commercially available in the U.S. since 2002, 2006, and 2009, respectively, for the treatment of adult patients who are at risk of sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator. Table 3 outlines the current international marketing approval for the device in the adult population. The LifeVest® has not been withdrawn from marketing in the United States or any foreign country.

Table 3: Current Marketing Approvals

Country Name	Approval or Certification Date	Approval or Certification Name and Number
European Union	09/02/1998	VDE Certificate / 0366/MDD/2039200-II
United States	12/18/2001	P010030
Australia	08/24/2006	ARTG 130631
Israel	03/07/2010	MOH Approval

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 this device. These potential adverse effects have been grouped into the following three (3) risk categories:

1. Therapy Related
   - Failure to sense and detect a treatable arrhythmia resulting in death.
   - Unsuccessful cardioversion or defibrillation resulting in death or disability.
   - Inappropriate shock causing abnormal heart rhythms, including fatal rhythms.
   - Pacemaker damage or resetting.
   - Superficial skin burns resulting from a shock.
   - Pain from a conscious shock.

2. Morbidity Associated with Wear
   - Allergic dermatitis due to sensitivity to materials used in construction that are held against the skin.
   - Skin infections (e.g., monilial or bacterial) secondary to moisture trapping and

continuous skin contact.
- Minor skin rashes from irritation and heat trapping.

3. External Device Interactions
   - Ineffective cardioversion/defibrillation by another external defibrillator if the LifeVest® device is not removed from patient as advised by the garment label.
   - Fire hazard in the presence of a high oxygen concentration.
   - Bystander shock from patient contact during a treatment event.

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

IX. SUMMARY OF PRECLINICAL STUDIES

All pre-clinical information used to demonstrate the safety and effectiveness of the physical LifeVest® device has already been reviewed by FDA under the original PMA (P100030) and subsequent supplements. No new pre-clinical information to demonstrate the proper functionality of the physical LifeVest® device was needed or provided in support of this PMA Panel-Track Supplement as the device did not change. A brief description of the non-clinical tests follows, but additional information can be found in P010030.

- Biocompatibility Testing
- Engineering Bench Testing
- Software Validation Testing
- Electromagnetic Compatibility Testing
- Electrical Safety Testing
- Environmental Testing
- System Validation Testing
- Simulated Use Testing

Some additional Human Factors information was provided in this submission to demonstrate the ability of any new patients being included in the Indications for Use to safely operate the device. This information was sufficient to justify that ability without the need for a new Human Factors study.

X. SUMMARY OF PRIMARY CLINICAL STUDIES

The clinical information below represents the additional information provided within this PMA Supplement in support of an expansion of the indications for use of this device to include pediatric patients. This information in combination with the extensive clinical experience with the device in adult patients (P010030), which can be extrapolated to the pediatric patients being incorporated into the indications for use, is sufficient to demonstrate the safety and effectiveness of this device for those pediatric patients.

As of November 8, 2012 publications in the literature have reported the use of the LifeVest® in 248 pediatric patients, aged 3-17, and 510 young adults, aged 18-21. The total duration of use for patients age 3 to 21 is 65,247 days, with an exposure mean of 3.2 months (range: <1 day to 39.0 months). The average daily wear time for patients age 3 to 21 is 16.6 +/- 6.2 hours.

Data provided by Zoll Manufacturing Corporation has shown the ability of the LifeVest® to successfully convert a sudden cardiac arrest to a life-sustaining rhythm in patients as young as thirteen (13). Four (4) patients in the 3-17 age group (indications for use: Wolf-Parkinson-White syndrome (WPW,) Cardiomyopathy (CM,) Tetrology of Fallot, and Congenital Heart Disease (CHD)) and five (5) in the 18-21 age group (indications for use: CM for all five (5)) experienced SCA during LifeVest® use that was successfully converted to a life sustaining rhythm. Table 4 provides further detail on the pediatric patients receiving an appropriate treatment with the LifeVest®.

Table 4: Pediatric Patients Receiving Appropriate Treatment

Patient	Age	Wear Duration (Days)	Indication for LifeVest® Use	Treatment Summary	Energy Delivered (Joules)	Reason for Ending LifeVest® Use
1	13	78	Congenital heart disease	1 appropriate treatment	151	Heart transplant
2	14	3	Cardiomyopathy	1 appropriate treatment	150	Received ICD
3	15	55	Wolf-Parkinson-White syndrome	1 appropriate treatment	150	Received ICD
4	16	60	Tetrology of Fallot	4 appropriate treatments	152-154	Improved ejection fraction
5	19	75	Cardiomyopathy	1 appropriate treatment	150	Other
6	19	139	Cardiomyopathy	1 appropriate treatment	150	Received ICD
7	20	119	Peripartum cardiomyopathy	1 appropriate treatment	151	Received ICD
8	21	22	Cardiomyopathy	3 appropriate treatments	150	Received ICD
9	21	236	Cardiomyopathy	2 appropriate treatments	150	Death

Published Reports on LifeVest® Use with Pediatric Patients

There are three (3) peer-reviewed articles on the use of the LifeVest® specifically in the pediatric population.[1,2,3] One recent paper describes four (4) pediatric patients prescribed a WCD from a single site.[2] All carried a diagnosis of anthracycline-induced cardiomyopathy. None of the patients had an appropriate or inappropriate shock. Two (2) patients had documented noncompliance with wear, which resulted in failure to detect and treat a life-threatening arrhythmia in one (1). Figure 2 describes the patient demographics and clinical characteristics for the pediatric patients describe in this article. While no patients received an appropriate treatment in this study, no patients received an inappropriate treatment despite the inappropriately detected rhythm caused by ECG noise. The paper concluded that the WCD is a short-term alternative for children at risk

for SCD, who can be properly fit with the WCD, where the risk of ICD use is greater than the benefit.[2]

Table I.

Patient Demographics and Clinical Characteristics

Patient	Age yrs	Gender	Weight (kg/ BSA)	Diagnosis	LVEF	History of Arrhythmia	Indication for ICD*	Listed for Transplant	Length of Wear (days)	Device Discharge	Compliant with Wear
1	14	M	48.4/1.5	ACM	68%	VF	2	No	30	N	No**
2	9	M	28.1/1.0	ACM	13%	NSVT	1	No	121	N	No**
3	15	F	41.9/1.3	ACM	16%	NSVT	1	Yes	67	N	Yes
4	17	F	77.5/1.9	ACM	26%	NSVT	1	Yes	49	IC	Yes

ACM = anthracycline-induced cardiomyopathy; VF = ventricular fibrillation; NSVT = nonsustained ventricular tachycardia; IC = inappropriate rhythm detection and charging of the device but no discharge due to voluntary deactivation by patient; N = none.
*Indication for ICD: 1 = primary prevention of sudden cardiac death based on an ejection fraction less than 35% and NYHA class III heart failure symptoms; 2 = secondary prevention based on a history of prior life-threatening arrhythmia.
**Patient 1 had a VF arrest while not wearing the device properly. Patient 2 self-discontinued use of the WCD without notifying the prescribing physician.

Figure 2: Table provided by Everitt et al.[2]

In a paper by Collins et al., 81 multi-site WCD patients from 9-18 years old, and 103 patients aged 19-21, were retrospectively reviewed.[3] In patients aged 19–21 years, there were five (5) appropriate treatments in two (2) patients and one (1) inappropriate treatment in a single patient. In patients ≤18 years of age, there was one (1) inappropriate therapy (included in the inappropriate treatments in Table 4), due to sinus tachycardia and artifact, and one (1) withholding of therapy due to a device-device interaction. Compliance was generally similar to adults among these younger patients, with an average daily use of 19 hours, and non-compliance or comfort issues only being recorded for 7-11% of patients. This paper concluded that the WCD could be an appropriate therapy for pediatric patients who are at risk for SCA, as they had two (2) appropriate treatments in their young adult population (age 19-21). However, they had no appropriate treatments in their pediatric population (age 9-18).

The third paper by LaPage et al., published prior to the two (2) papers discussed above, detailed the fatal device-device interaction between the wearable defibrillator and a unipolar epicardial pacemaker.[1] Such interactions are not unique to pediatric patients nor are they unique to wearable defibrillators, being copiously described in the ICD and AED literature. LifeVest® manuals have included specific warnings about pacemaker interactions since the initial FDA approval. These warnings advise physicians to use appropriate caution when prescribing the LifeVest® device to a patient who is dependent on a pacemaker.

Reported adverse events

There was only one (1) serious adverse event reported in the literature for pediatric patients using the LifeVest®. This event is described in a paper by LaPage et al., which summarizes the withholding of therapy caused by a pacemaker interacting with the LifeVest®.[1] During this event the patient developed a polymorphic ventricular tachycardia, which was detected by the LifeVest® device. However, the LifeVest® treatment algorithm was terminated because of inconsistencies in the arrhythmia waveform caused by unipolar ventricular pacemaker artifacts. The patient's VT

degenerated to VF and the patient expired. LifeVest® manuals include specific warnings about pacemakers interacting with the device.

As of November 8, 2012, there have been three (3) incidents reported by Zoll of inappropriate treatments for pediatric patients. These inappropriate events are summarized in Table 5. The rate of inappropriate treatments per patient day of use for pediatric patients is 0.00005. This is approximately five (5) times less than that of adult patients, which is 0.00024 inappropriate treatments per patient days of use. Two (2) of the three (3) inappropriate treatments were induced by artifact noise combined with the patient failing to press the response buttons. The third inappropriate treatment was caused by noise from the patient wearing the device over her clothes.

Table 5: Pediatric Patients Receiving Inappropriate Treatment

Age	**Wear Duration (Days)**	**Indication for LifeVest® Use**	**Treatment Summary**	**Energy Delivered (Joules)**	**Reason for Ending LifeVest® Use**
17	23	Cardiac Arrest	1 inappropriate shock caused by noise	150	Other
17	87	Infection from ICD	1 inappropriate shock caused by noise	150	Planned finish
19	130	Cardiomyopathy and tachyarrhythmias	1 inappropriate shock caused by noise, patient was wearing the device over clothes	150	Passed away, patient not wearing device at time of death

Minor rash (from heat or irritation) is an anticipated low frequency adverse event, where the patient can notify their physician for a recommended resolution method. Approximately 3.3% of pediatric LifeVest® patients were affected by minor rashes from device use.

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. Zoll provided this information in the original PMA, and in this submission, for the adult population, which was used to support approval in the pediatric population. Zoll provided two published papers[2,3] from the literature to support this submission and does not have any disclosable financial interests/arrangements with those investigators. All other articles cited in this document

were brought into the review by FDA during FDA's review, thus the applicant is not required to provide information for those investigators. The information provided does not raise any questions about the reliability of the data.

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

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this supplement was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the risk benefit profile of the device is well established in the adult population (P010030), the device has not changed, and P010030 was not taken to panel because the risks to health in external defibrillation are clearly characterized and well known by the medical community and no new clinical issues related to safety and effectiveness were identified. The additional information that was submitted for pediatric patients did not raise any new questions of safety or effectiveness. Therefore, it was determined that the clinical issues raised by this supplement are similar to those previously reviewed by this Panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

Data from the literature cited above has shown the LifeVest®'s ability to successfully convert a sudden cardiac arrest to a life-sustaining rhythm in patients as young as thirteen (13). Four (4) patients in the 3-17 age group and five (5) patients in the 18-21 age group experienced a sudden cardiac arrest during LifeVest® use that was successfully converted to a life-sustaining rhythm. While a successful shock was not reported in a patient younger than 13 the AHA dosing guidelines for external defibrillation suggest that we can expect an appropriate shock to be effective in any patient whom meets the weight requirement stated in the Indications for Use. Timely defibrillation is the single most important factor in saving either adult or pediatric patients from SCA due to ventricular tachyarrhythmias. The earlier defibrillation therapy can be provided, the higher the likelihood of survival. The time from arrhythmia onset to defibrillation provided by a WCD is designed to be less than 60 seconds. In adults, there is an approximately 10% decline in mortality for every minute a shock is delayed after collapse and resuscitation in children is expected to follow a similar pattern.[4] Thus, rapid defibrillation is a large benefit from LifeVest® use.

B. Safety Conclusions

The clinical information provided in this submission did not identify any additional safety concerns associated with use of the LifeVest® in patients under the age of 18, who are of the appropriate size for the device, than were seen in the complete clinical study for patients over the age of 18 submitted in the Original PMA.

C. Benefit-Risk Conclusions

The LifeVest® currently has PMA approval for use in adult patients who are at risk for SCA and are not candidates for or refuse an implantable defibrillator. The LifeVest® provides these adult patients protection during their changing medical condition and until a permanent risk of SCA is established. A patient's condition frequently improves from the benefits of medical therapy, including meaningful increases of ejection fraction. However, medical therapy and stabilization often takes three (3) months or more, and during these periods of heightened risk LifeVest® use can prevent SCD. Although similar to an ICD, a WCD provides the physician with an additional non-invasive option to manage patients with temporary or changing risk of SCD. For example, pediatric patients awaiting heart transplant are at a high risk for SCD, yet the anticipated need for protection may only be a few months before cardiac transplantation occurs.[2] The noninvasive LifeVest® is an option for temporary SCA risk circumstances.

Collins et al. states that any patient who, for medical or social reasons, would want to have a waiting period prior to the placement of a permanent ICD, may be included in this population.[3] They list patient scenarios such as ICD infection requiring device removal, prolonged antibiotic treatment prior to implanting a new device, or an ICD malfunction prior to scheduling a device extraction or revision surgery as appropriate for WCD use.[3] Another potential population would be those patients at a high risk for SCD who are awaiting cardiac transplant. These patients may only require SCD protection for a few months prior to transplant. The LifeVest® provides an alternative clinical management option for this waiting period.

Although rare, SCD does occur in children, at a rate of about 0.6-6.2/100,000 children in the U.S. per year.[5] Most of these deaths are due to arrhythmic causes. As described by Topjian et al., important factors that influence survival outcomes for pediatric patients who experience a SCA event include preexisting conditions, environment in which the cardiac arrest occurs, length of time from collapse before resuscitation, initial electrocardiographic rhythm detected, and quality of the basic and advanced life support interventions administered.[6] The American Academy of Pediatrics has also issued a policy statement listing the cardiac disorders predisposing youth to SCA.[7] This list includes structural/functional causes such as; cardiomyopathy whether congenital or acquired, coronary artery anomalies, aortic rupture, myocarditis, left ventricular outflow tract obstruction, mitral valve prolapse, atherosclerotic disease and congenital heart disease. The policy also lists primary arrhythmic disorders such as long QT-syndrome (LQTS), Wolf-Parkinson White syndrome (WPW), Brugada syndrome, catecholaminergic polymorphic ventricular tachycardia, short QT syndrome SQTS and complete heart block. Additionally, Triedman et al. described the forms of heart disease associated with SCD in the pediatric population are hypertrophic cardiomyopathy, LQTS, anomalous coronary arterial anatomy and WPW.[8]

The LifeVest® is a prescription device, where the patient's physician determines the VT/VF rate thresholds and shock energy level for the patient. This close physician oversight provides further reassurance that the device will deliver a shock with appropriate energy according to the patient's weight. Seventy five (75) joules is the lowest energy level the LifeVest® is currently able to deliver for treatment. According to the American Heart Association (AHA) guidelines, 2-4J/kg is the highest recommended energy level for effective defibrillation therapy for pediatric patients. In order for pediatric patients to be treated with an appropriate amount of energy with the LifeVest® device, they must meet the minimum required weight range of 18.75 to 37.5kg (75J ÷ 2 to 4J/kg = 18.75 to 37.5kg). The average 8 year old weighs 25kg and the Centers for Disease Control (CDC) growth charts indicate that both boys and girls 8 years of age meet this weight requirement with their average weight ranging from 20-35kg. For an older pediatric patient who weighs significantly more than 37.5 kg the physician can select up to 150 J for optimal dose.

The chest circumference limit stated in the Indications for Use is based on the garments sizes currently marketed with the LifeVest® device.

The most commonly reported adverse event associated with LifeVest® use is skin rash. The most serious adverse event is death from arrhythmia induction due to inappropriate shock. VT/VF following an inappropriate shock from a wearable defibrillator was reported to occur four (4) times out of 265 inappropriate treatment patient-events (1.5% of inappropriate shocks).[9,10] As of March 2013, inappropriate treatments have occurred in approximately 1,326 adult patients. About 171,055 months of patient use have occurred during commercial use for an incidence of 0.008 inappropriate shock episodes per patient month of use. Only two (2) deaths, however, have resulted from arrhythmia induction secondary to an inappropriate shock as most VT/VF inductions are non-sustained and the LifeVest® usually treats those that are not. Since the initial LifeVest® clinical trials, there have been 1,237 treatment episodes for sustained ventricular arrhythmias, while the LifeVest® was worn. As of March 2013, three (3) pediatric patients have received an inappropriate treatment and none of the events led to injury or illness. The experience of an inappropriate treatment may be painful and startling, but rarely causes heart damage or arrhythmia.

The Human Factors information in this submission indicates that pediatric users being included in the indications under this submission are generally capable of using the primary safety feature of the device. By pressing a button on the device control unit, the patients can prevent treatment in the unusual case when the device intends to deliver a shock when no shock is necessary as determined by the patient being conscious when the device enters the mode preparing for shock treatment.

The consideration of the above mentioned elements of this system provides assurance for the safe use of this device. The considerations include lower size limits that were chosen because the smallest garment and electrode belt could fit the typical body of a child of this age and older, and the energy levels that the pediatric patients could receive would be within the accepted therapy dose for these type of patients. Based

on the information reviewed, FDA believes that the device does not pose an unreasonable or significant risk of injury, and that the probable benefit to health outweighs the risk of injury from its use.

D. Overall Conclusions

FDA found that the application contains sufficient clinical data and information to demonstrate the safety and effectiveness and support approval of the device for the proposed pediatric population.

XIII. CDRH DECISION

CDRH issued an approval order on December 17, 2015. The final conditions of approval cited in the approval order are described below.

OSB Lead PMA Post-Approval Study – *LifeVest in those under 18 years of age*: A study will be conducted as per protocol dated February 19, 2015, Version 5 included in P010030/S056. The study will consist of a serial, prospective data collection of patients under 18 years of age utilizing the LifeVest® Wearable Cardioverter Defibrillator who meet the proposed indication for the treatment of life-threatening arrhythmias. The data will be collected via medical order database, device generated records, and customer call reports for each device use. Patient demographics collected will include age, gender, and ICD-9 code(s) describing the patient's condition. Performance information will include daily compliance with use, duration of use, appropriate therapy delivery, ECG recordings during appropriate therapy delivery, and any available description of the circumstances found within the Call Report Database. Safety data to be included are inappropriate defibrillation therapy delivery, ECG recordings during inappropriate therapy delivery and any available description of the circumstances found within the Call Report Database, and adverse events reported to ZOLL through the customer support or technical support departments. The data on the first 150 patients who meet the proposed indication will be collected and data will be obtained from the returned device.

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

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

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

Post-approval Requirements and Restrictions: See approval order.

XV. REFERENCES

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