

SUMMARY OF: P010030/S031

**LIFEVEST WEARABLE DEFIBRILLATOR MODEL 3000, 3000S, 3100 and 4000/
ZOLL LIFECOR CORPORATION**

EXECUTIVE SUMMARY/BACKGROUND

In this submission the sponsor requested approval of several hardware design changes and a software driver update. The changes are:

1. Add several (b) (4) Components. The devices affected by this change are models: WCD 3000, WCD 3000S, WCD 3100 and WCD 4000.
2. Add an (b) (4) for the high voltage, (b) (4) in the LifeVest 4000 monitor.
3. Add a (b) (4) t (b) (4) and (b) (4) in the LifeVest 4000 monitor and in the LifeVest 4000 charger and (b) (4) method.
4. Add a (b) (4) (b) (4) in the LifeVest 4000 Electrode Belt.

DESCRIPTION OF CHANGES/ REASON FOR SUPPLEMENT

Add Several Lead-free Alternate Components

These hardware changes are to add several (b) (4) components because the European Directive for the Restriction of Hazardous Substances (RoHS) has resulted in many (b) (4) from traditional (b) (4) for component leads to (b) (4). The sponsor claims that this switch over to (b) (4) has had no impact on the company since they use a (b) (4) (b) (4) at their (b) (4).

The components have exactly the same specifications or have the same operating specifications as the respective components which they replaced. The only change was the replacement of (b) (4). The risks and necessary mitigations to justify the use of components with (b) (4) applied to their (b) (4) were addressed. (b) (4) and found to have (b) (4) (in worst case) of (b) (4) length where critical spacing distance was (b) (4).

**Add an (b) (4) for the High Voltage, (b) (4)
in the LifeVest 4000 Monitor**

This hardware change is for the addition of an (b) (4) for the high voltage capacitors used in the LifeVest 4000 monitor. The (b) (4), was added to (b) (4) (b) (4).

Add a Replacement (b) (4) c and (b) in the LifeVest 4000 Monitor and in the LifeVest 4000 Charger and (b) (4)

(b) (4)

Add a Replacement (b) (4) in the LifeVest 4000 Electrode Belt

(b) (4)

INDICATIONS FOR USE

The LifeVest system is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator.

DEVICE DESCRIPTION

The LifeVest device is a wearable cardioverter defibrillator worn by a patient at risk for sudden cardiac arrest (SCA). It monitors the patient's heart continuously and, if the patient goes into a life-threatening arrhythmia, can deliver an electrical shock to restore the patient's heart to a normal rhythm. The LifeVest device consists of two main components: (1) an electrode belt and garment that surrounds the patient's chest, and (2) a monitor that the patient wears around the waist or from a shoulder strap.

Washable garments are available in sizes to suit most patients. The LifeVest device's electrodes are dry and non-adhesive to provide patient comfort. The device contains push buttons and a display for the user, as well as a speaker for sounding alarms and voice prompts. When the device detects a treatable arrhythmia, an alarm sequence begins, giving a conscious patient time to stop the treatment. If the patient presses the two "response" buttons at any time during the treatment sequence, the alarms stop and no shocks will be delivered. If the patient does not respond, the device continues to give alarms and verbal warnings to bystanders that a treatment shock is about to be delivered. Gel within the electrodes is released just prior to delivering the treatment shock in order to deliver the shock most efficiently. The entire event, from arrhythmia detection to delivery of the shock treatment, typically takes less than one minute. If the arrhythmia continues after the first shock, up to 5 shocks may be given in a treatment sequence.



Review Summary

As described in the previous section, all the changes made to this device consist of (b) (4). There were no deficiencies for the electrical safety of the change in (b) (4).

(b) (4)

The software review indicated that in only (b) (4) changes necessitated a change to the (b) (4). However, the requirements, architecture, and design of the software are unchanged. In addition, since these changes are only to (b) (4) one part for another, the risk assessment is unchanged. There are no concerns for software.

Since the high voltage capacitors are critical for the shock delivery, it was necessary to confirm that the device delivers the same shock waveform with the new capacitors as the shock delivered by the device with the current capacitors. The data submitted demonstrates that the new (b) (4) deliver the same shock waveform as the (b) (4) at all the energies and impedance requested.

(b) (4)

Zoll stated that P010030/S031 supplement (b) (4)

(b) (4)

. All the other issues were resolved.

Recommendation

Approval