# Memorandum

**DATE:** April 18, 2011

**FROM:** , Scientific Reviewer
FDA/CDRH/ODE/DCD/PDLB

**SUBJECT:** P010030/S023 – Lead Review
Lifevest Wearable Defibrillator
*Zoll Lifecor Corporation.*

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**TO:** The Record

**RECOMMENDATION:** **APPROVAL**

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, Lead Reviewer, PDLB Date

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, Chief, PDLB Date

## EXECUTIVE SUMMARY

This PMA supplement was submitted to gain approval for a change to the bare board assembly of the LifeVest Device WCD4000 Wearable Cardioverter Defibrillator. Included in this change is a new Printed Circuit Board (PCB) that eliminates the work-arounds of the previous revision of the board. Also included is a change to the solder finish from (b) (4) ((b) (4)) to (b) (4) ((b) (4) ), an alternate LCD connector, addition of (b) (4) epoxy to the large BGA chip, and slightly (b) (4) capacitors. No performance changes or enhancements to the overall product are being claimed. The changes should be transparent to the user and does not change the functionality of the product.

The PCB changes are being incorporated to minimize the manufacturing time, increase yield, and reduce the cost of doing manual labor to cut traces, add jumper wires, and place certain components by hand. This is stated to be the primary reason to re-spin the PCB. The

submission does not give a direct comparison between the current version of the board and the proposed board. Included in this change is a different connector for the LCD. The existing connector for the LCD is prone to crack during transport and manufacturing. The alternate connector selected has a more rugged connector body and also required the mounting pads and traces to change. The sponsor did not indicate if there were any field related issues that necessitated the LCD connector change. The sponsor is also changing the plating finish on the external solderable surfaces of the PCB. The proposed change moves from the current (b) (4) (b) (4) ((b) (4)) to (b) (4) ((b) (4) ).

A full hardware evaluation was conducted which included functional testing of the proposed system. The system performance and design specifications have not changed and the testing validates this claim. Additional vibration and environmental ((b) (4) (b) (4) ) testing was done and passed successfully. The testing seems to justify that performance of the device has not been compromised due to the design change and looks to be acceptable.

## BACKGROUND

The file was originally submitted as a 30-day notice for manufacturing changes. The review as originally conducted by in the Office of Compliance. The 30-notice was rejected due to the design changes to the PCB. in PDLB concurred that the changes qualified as a design changes and a 180-day notice would be required.

## INDICATIONS FOR USE

The “Indications for Use” have not changed.

## CONTRAINDICATIONS

The Contraindications have not changed.

## DETAILED DESCRIPTION OF CHANGES

The sponsor changed the artwork on the 10M0971 bare board. This board is used in the 10A0971-A01 and 10A0971-A02 assemblies. The current board requires multiple modifications that are performed by hand at the contract manufacturer. The modifications included trace cuts, jumper wires and additional component installations. The changes to the proposed bare board eliminate these rework steps.

The sponsor changed the finishing on the solderable surfaces of the bare board. They changed the process from (b) (4) (b) (4)) to (b) (4) (b) (4) ((b) (4) ). The sponsor stated that the (b) (4) process and finish provides a flat surface for surface mount technology (SMT) parts, high reliability, and a wide process window. This process is also RoHS (Lead-free) compliant.

The sponsor has changed the LCD touchscreen connector used in their monitor. The current connector requires special handling to prevent cracking of the plastic housing. An alternative connector was selected which has a more rugged connector body. This required a change to the mounting pads of the connector. The artwork on the board was modified accordingly to accept the proposed connector.

The sponsor is adding a epoxy (b) (4) under the large BGA chips on the circuit board. The (b) (4) is designed to minimize cracking of the solder joints by reducing the mechanical stress caused by thermal expansion or mechanical vibration or flexing. (b) (4) was selected as the (b) (4)l.

The sponsor is changing the voltage requirements of (b) (4) capacitors. They are increasing the voltage requirements to increase yields. The change to the components requires a larger SMT packages and a slight artwork change was required to fit the new size package.

## BIOCOMPATIBILITY/MATERIALS

The proposed changes only pertain to the bare boards which are non-patient contacting. There are no changes to patient contacting materials and therefore no biocompatibility review was necessary.

## VERIFICATION AND VALIDATION TESTING

Process validation was conducted by the sponsor on (b) (4) boards using the proposed board design. The sponsor (b) (4) analyzed (b) (4) out of the (b) (4) boards for evaluation of solder wetting and fillet length, width and height in accordance with (b) (4) requirements. In addition (b) (4) was (b) (4) tested for cross-sectional analysis. During analysis it was found that the solder mask thickness was below the (b) (4) specification. The sponsor conducted a dielectric strength test on the out of spec board and found that the dielectric strength was above the (b) (4) minimum dielectric strength required by the sponsor.

An Operational Qualification (OQ) was conducted on the proposed board with the proposed process. The OQ included the following process checks:

- (b) (4)
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- (b) (4)
- (b) (4)

The OQ verified that the proposed boards and process passed all inspection and a full

functional test was performed. Every step was verified using a First Article of Inspection. This verified that all parts were placed according to the design, and that the proposed solder process is correct and valid. This is acceptable.

The sponsor states that engineering validation and verification testing were successfully conducted on proposed board design. Testing included electrical hardware test, EMC testing, mechanical random vibration testing, and validation testing of production-level monitors. The validation testing was performed on (b) (4) monitors, while all other testing (b) (4) used (b) (4) . This testing seems to be complete and is acceptable.

An Installation Qualification, Operational Qualification, and Performance Qualification (IQ/OQ/PQ) was conducted on (b) (4) articles. The installation qualification ensures that the production system is installed as designed and documented. The operational qualification ensures that proper equipment operation and process parameters are correct and will produce acceptable results under normal operating conditions. The performance qualification ensures the process is effective and reproducible. The complete IQ/OQ/PQ is in the submission under Appendix A. The process looks to be complete and is acceptable.

Along with a list of hardware validation tests (clock testing, pin voltage tests, etc.) the sponsor performed several functional tests including:

- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)

This testing passed successfully and demonstrates that there is no performance difference between the current design and the proposed design. This testing looks to be complete and is acceptable.

## MECHANICAL SAFETY

There are no changes to the mechanical safety of the device and therefore no mechanical safety review was necessary.

## PACKAGING, SHELF LIFE, AND STERILIZATION

According to the submission there are no changes to the shelf life, packaging, or sterilization.

## SOFTWARE

There are no changes to the software of the device and therefore no software review was necessary.

## LABELING

There are no changes to the labeling of the device and therefore no labeling review was necessary.

## ANIMAL STUDIES

There were no animal studies presented or required.

## CLINICAL DATA

There was no pre-clinical information presented or required.

## RECOMMENDATION

Based on all of the information submitted, I recommend that the sponsor receive an **approval** letter.