DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax: (215) 597-0875 Industry Information: www.fda.gov/oc/industry	05/22/2014 - 06/20/2014* FEI NUMBER 3008642652

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Marshal Linder, President/COO

FIRM NAME	STREET ADDRESS
Zoll Lifecor Corporation	121 Gamma Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pittsburgh, PA 15238-2919	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically,

a) an MDR report was never submitted after receiving or otherwise becoming aware of information that reasonably suggests that a (b) (4) device (model #s 3000, 3100, & 4000) may have caused or contributed to a death or serious injury.

1) Complaint Report Form with Call Report # (b) (4) documents that a 76 year old patient received one inappropriate shock, causing "2nd and 3rd degree burns on her back" and "knocked her 7-8 feet". Furthermore, no further investigation or follow-up to this patient's injuries was performed.

b) three MDR reports were not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a (b) (4) device (model #s (b) (4)(b) (4)) may have caused or contributed to a death or serious injury.

1) Complaint Report Form with Call Report # (b) (4) documents that on 02/11/2014, a 69 year old female received two inappropriate shocks, and the patient "fell and broke her wrist". The MDR report with Mfr Report # 3008642652-2014-01073 was subsequently filed on 04/04/2014.

2) Complaint Report Form with Call Report # (b) (4) documents that on 08/15/2013, a 75 year old male received one appropriate shocks, and "the patient suffered 2nd-3rd degree burns". The MDR report with Mfr Report # 3008642652-2013-02661 was subsequently filed on 09/16/2013.

3) Complaint Report Form with Call Report # (b) (4)(b) (4) documents that on 04/26/2014, a 68 year old male received two appropriate shocks, causing the patient to "fall off of the roof". The MDR report with Mfr Report #

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3008642652-2014-01663 was subsequently filed on 05/28/2014.

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically,

a) twenty-four MDR reports were never submitted after receiving or otherwise becoming aware of information that reasonably suggests that a (b) (4) device (model #s (b) (4)(b) (4)(b) (4)) has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. (b) (4) Complaint Report Forms document that patients received one or more inappropriate shock treatments due to noise artifact and/or vibration caused by loud-noise environments and/or high vibration activities.

b) ten MDR reports were not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a (b) (4) device (model #s (b) (4)(b) (4)(b) (4) has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

OBSERVATION 3

Complaint files are not adequately maintained.

Specifically, two complaints that reasonably suggest that a (b) (4) device (model #s (b) (4)(b) (4)) may have caused or contributed to a death or serious injury were not thoroughly investigated and/or evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR 803.

a) Complaint Report Form with Call Report # (b) (4) documents that an 81 year old female received one inappropriate shock, causing "two hematomas on her cheek, chin, a bloody lip and her face is swollen". Furthermore, no further investigation or follow-up to this patient's injuries was performed.

b) Complaint Report Form with Call Report # (b) (4) documents that a 93 year old male received four inappropriate shocks while driving, and the "patient crashed car". Furthermore, no further investigation or follow-up to this patient's injuries was performed.

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OBSERVATION 4

Corrective and preventive action activities and/or results have not been documented.

Specifically,

a) no corrective and preventive action activities have been documented as a result of high noise artifact and/or vibration causing the (b) (4) device (model #s (b) (4)(b) (4)) to inappropriately deliver shock treatments to patients. Additionally, approximately half of all treatments delivered are inappropriate shocks, and (b) (4) complaints were observed in which noise artifact and/or vibration resulted in inappropriate shock treatments being delivered to patients.

b) no corrective and preventive action activities have been documented regarding the use of the (b) (4) device (model #s (b) (4)(b) (4)) in patients with cognitive and/or physical limitations. Additionally, (b) complaints were observed in which physical and/or cognitive disabilities limited the user from interacting with the device as intended.

c) no corrective and preventive action activities have been documented regarding bystander interference with the (b) (4) device (model #s (b) (4)(b) (4)(b) (4) Additionally, numerous complaints document that bystanders are interacting with the device, during cardiac events of patients, preventing treatment to be delivered.

OBSERVATION 5

The design was not validated under actual or simulated use conditions.

Specifically, the (b) (4) device (model #s (b) (4)(b) (4)(b) (4) was not adequately validated under actual or simulated use conditions. Noise artifact and vibration caused by various patient activities such as riding a motorcycle, riding a lawnmower, jogging, being in a loud noise environment, etc. routinely cause inappropriate shock treatments to be delivered to patients. Additionally, approximately half of all treatments delivered are inappropriate shocks, and (b) (4) complaints were observed in which noise artifact and/or vibration resulted in inappropriate shock treatments being delivered to patients.

OBSERVATION 6

Risk analysis is inadequate.

Specifically,

a) the risk analysis performed on the (b) (4) device's Information for Use manuals is inadequate (model #s (b) (4)(b) (4) (b) . The manuals do not contain any warnings or contraindications against lifestyle activities causing high noise artifact and vibration. Additionally, the (b) (4) marketing materials advertise that patients can continue their lifestyle with the use of the device, and the Patient Service Representative employees do not warn against such activities during the fitting and training session.

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b) the risk analysis performed on the (b) (4) device (model #s (b) (4) ((b)) is inadequate in that it does not consider the use of the device in patients with cognitive and/or physical limitations. Additionally, (b) complaints were observed in which physical and/or cognitive disabilities limited the user from interacting with the device as intended.

OBSERVATION 7

Management with executive responsibility has not reviewed the suitability and effectiveness of the quality system with sufficient frequency.

Specifically, the President/COO and six out of nine Vice Presidents did not attend all quarterly management review meetings during 2013 and 2014, as required per the standard operating procedure titled, (b) (4)(b) (4)(b) (4)(b) (4)".

- The President/COO did not attend a management review meeting during the 4th quarter of 2013.
- The Vice President of Engineering did not attend a management review meeting during the 4th quarter of 2013.
- The Vice President of Global Marketing and Clinical Operations did not attend a management review meeting during the 4th quarter of 2013.
- The Vice President of Finance and Administration/CFO did not attend a management review meeting during the 3rd quarter of 2013.
- The Vice President of Reimbursement did not attend a management review meeting during the 3rd quarter of 2013.
- The Vice President of U.S. Sales did not attend a management review meeting during the 4the quarter of 2013 or the 1st quarter of 2014.
- The Vice President of International Sales did not attend any management review meetings in 2013 or 2014.

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Observation Annotations

Observations intentionally left blank.

*** DATES OF INSPECTION:**
05/22/2014(Thu), 05/23/2014(Fri), 05/27/2014(Tue), 05/28/2014(Wed), 05/30/2014(Fri), 06/02/2014(Mon), 06/03/2014(Tue), 06/20/2014(Fri)

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