DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 596-7700 Fax:(781) 596-7896 Industry Information: www.fda.gov/oc/industry	07/29/2010 - 08/18/2010
	FEI NUMBER 3003521780

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gintaras A. Vaisnys, President

FIRM NAME	STREET ADDRESS
Defibtech, LLC	741 Boston Post Rd Ste 201
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Guilford, CT 06437-2714	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

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

Specifically, the firm reopened CAR 07-007 on 09/22/09 after receiving RMA 4594. The firm noted the risk assessment was reviewed and recalculated based upon seven field occurrences between May 2007 and August 2009. In the Field Action Review Board Decision Memo dated 9/22/07 they documented in that reopened CAR the firm recalculated the updated probability of occurrence calculation of "overshoot" as being low and the risk of occurrence (e.g. failure to shock) as decreasing over time as the battery voltage decreases in the "rationale for Decision" in that document. There is no documentation that the firm calculated the variability of discharge curves for the batteries sold with the AEDs marketed.

OBSERVATION 2

Rework and reevaluation activities have not been fully documented in the device history record.

Specifically, review of CAR 07-007 initiated on 6/4/07 documents the investigation into a production trend failure of nonconformance's of DDU-100 AEDs noted (b) (4) failures were observed during production. The root cause of the failures was determined to be "high battery voltage during AED charging that occurred when the battery was very new". A corrective measure was implemented to address the issue for all in house battery packs (Model 2800 battery packs) to address current and future production, however, all previously shipped 2800 battery packs were not affected as they were determined to be low risk with respect with an estimated probability of occurrence based on per unit per month failure rate.

The CAR references th(b) (4) failure rate noted as the "product trend rate", as noted on page 1, paragraph 1 of the CAR. Review of the firm's "Data Trending" operating procedure identified as Operational Procedure QOP-14-08 Revision A dated 5/3/06 (Current version Rev. D is dated 9/22/09) notes the data sources used to spot Nonconformance's (QOP-14-08 Revision A, page 5, Appendix 1 (Table)) as "Production Functional Assembly and test Data*Field Data**Complaint Data*Internal Audit Findings & Management Review Action Items". Review of the CAR 07-007 in the section titled "CAPA File as

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Closed on 2/29/2008" notes the failure mode of the 2800 battery pack was a failure to shock and due to an "overshoot charge on the battery pack" and an an error code of "SC1003" identifying the problem in production of 5 battery packs as reported on 6/4/2007. The firm performed a 100% check of the (b) (4) batteries in house at the time and identified the following line item entry batteries as not passing with an error code of "09999-0000" 37, 38, 61, 84, 95, 114, 152, 170, 188, 240, 338, 351, 359, 434, and (b) (4) for a total of (b) (4) failures for the same error code, not 6/481 as reported in the CAR.

Review of the "Weekly Production Trend Analysis for MPI" used by the firm to monitor production nonconformances for trend analysis for the following week endings which include the time frames covering the testing of the battery failures identfied above do not identifiy "SC 1003" as a failure mode in any of the data trend analysis, all of the line items identifying the "Error Code Description" are listed as "Other".

OBSERVATION 3

Products that do not conform to specifications are not adequately controlled.

Specifically, review of the 15 "Nonconforming Material Reports" identified as NMR 01-07000032, 33, 67, 141 167, 168, 176, 239, 240, 256, 274, 275, 276, 300, and 301filled out by the firm during the time period 4/9/2007 to 6/1/2007 for failed batteries identified under CAR 07-007 lack final disposition for these batteries (they remain open after three years).

OBSERVATION 4

Procedures to ensure equipment is routinely calibrated have not been adequately established.

Specifically; the procedure for Inspection, Measuring and Test Equipment, QOP-11-01, Rev. B, does not identify the process to identify, remove, and evaluate equipment which is due to be calibrated.

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Observation Annotations

Observation 1: Promised to correct.
Observation 2: Promised to correct.
Observation 3: Promised to correct.
Observation 4: Promised to correct.

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