DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	7/18/2017-8/1/2017* FEI NUMBER 3006967710

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Richard R. Hoffman , President

FIRM NAME	STREET ADDRESS
CME America, LLC	14998 W 6th Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Golden, CO 80401-6587	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 I OBSERVED:

OBSERVATION 1

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, your firm was unable to provide documentation of all validation activities conducted on the (b) (4) Molding machines (SN (b) (4)) used in the manufacture of pump parts for the BodyGuard Infusion Pumps.

OBSERVATION 2

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically,

Your firm's Nonconformance SOP (QA-12, Revs 9-12) requires notifying QA immediately upon identification of a nonconformance and documentation on a Non-conformance Record for evaluation and disposition, including determining the need for an investigation.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kathleen S Tormey, Investigator	X Kathleen S Tormey Investigator Signed By: Kathleen S. Tormey -S Date Signed: 8/1/2017	8/1/2017

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Richard R. Hoffman , President	
FIRM NAME CME America, LLC	STREET ADDRESS 14998 W 6th Ave
CITY, STATE, ZIP CODE, COUNTRY Golden, CO 80401-6587	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

7 of 11 device history records (DHRs) reviewed did not include documentation of the identification of existing nonconformances (A10074, A10963, A10959, A11130, A11153, A11117, and A11123).

Additionally, your firm initiated NCR 2017-018 on 1/24/17 for pumps failing for a variety of differences from manufacturing during (b) (4). Your investigation that was completed on 3/13/17 documents the cause as "craftmanship" with the disposition to rework the devices. This NCR addresses several DHRs including A10963 and A10959; however, the manufacturing operations were performed on these DHRs on 4/12/17 and 4/25/17, approximately one month after the nonconformance investigation was completed.

OBSERVATION 3
A device master record has not been adequately maintained.

Specifically, the Device Master Record (DMR) for the BodyGuard 323 Infusion Pump does not include or refer to the location of all production and process specifications, including production methods and procedures and complete labeling specifications. For example, the DMR does not include revisions to your manufacturing operations including pump disassembly, assembly and patient guide.

OBSERVATION 4
Potential suppliers were not evaluated and selected based on their ability to meet specified requirements.

Specifically,
Your firm maintains a Supplier Quality Assurance procedure (QA-14, Rev 12, dated 9/15/16) to define the requirements and process controls to ensure all product and services meet quality standards and conform to specified requirements. This procedure includes requirements based on the categorization of the supplier.

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The procedure requires completion of a supplier performance evaluation and analysis of supplier quality data for Category (b) (4) suppliers. Sections 7 and 8 of the Supplier Quality Assurance procedure require generation and analysis of performance metrics, as well as evaluation of NCR data and CAPA history. You identified the contract manufacturer of PCB assemblies, molded components and machined components for infusion pumps as a Category (b) (4) supplier. Your most recent evaluation and approval of this supplier dated 3/30/17 does not include a review of CAPA history or complete analysis of NCR and performance metrics.

This is a repeat observation.

Annotations to Observations

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

***DATES OF INSPECTION**

7/18/2017(Tue),7/19/2017(Wed),7/20/2017(Thu),7/21/2017(Fri),7/25/2017(Tue),7/26/2017(Wed),7/28/2017(Fri),8/01/2017(Tue)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kathleen S Tormey, Investigator	X Kathleen S Tormey Investigator Signed By: Kathleen S. Tormey -S Date Signed: 8/1/2017	8/1/2017