DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	10/29/2013 - 11/06/2013* FEI NUMBER 1316297

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Bruce B. Whitcavitch, Jr., Vice-President of Manufacturing/Operations

FIRM NAME	STREET ADDRESS
Epimed International, Inc.	141 Sal Landrio Dr Crossroads Business Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Johnstown, NY 12095-3835	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

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been established.

Specifically, you are fielding complaints and remanufacturing the (b) (4) product, a product line you (b) (4), without established production & process control procedures for the product.

For example, your firm has received complaint #(b) (4) dated 8/6/13, complaint #(b) (4) dated 9/16/13 and complaint #(b) (4) dated 10/11/13 for the (b) (4) serial numbers (b) (4). Your firm disassembled and/or repaired all three probes and sent them back to the customers for use without the use of established production & process control procedures.

OBSERVATION 2

Procedures for design change have not been established.

Specifically, Engineering Change Order (ECO) (b) (4) dated 09/15/2006 changed the production specification for the mechanical requirement of bond strength on the Extension Sets, Project (b) (4), from (b) (4) lbs. The Quality Control inspection manufacturing procedure, SOP-457 'Extension Set Bond Strength' was updated at Rev.6 on 2/3/2011 from having an action limit of (b) (4) lbs. to and action limit of (b) (4) lbs. However, your firm did not update the design specifications in the Extension Sets design file, Project (b) (4) for this attribute or carry this specification change, implemented via ECO (b) (4), through the entire design review process to ensure the specification change does not adversely affect the overall device. Additionally, the source for the change in specification was not adequately documented.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Catherine M. Beer, Investigator	11/06/2013

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OBSERVATION 3

Procedures for design validation have not been established.

Specifically, design validation procedure SOP-705 Rev. 5 'Design Validation' does not provide adequate instruction to ensure all deviations from acceptance criteria are identified and corrected prior to the approval of the validation data.

For Example, 'Design Validation (b) (4) Catheter' for Project No. (b) (4) dated 8/16/2013 was completed with a missing datapoint for 'Shear Resistance' of the catheter. The acceptance criteria of the validation required an average score of (b) (4) or higher on this criteria (and all others) and also stated any individual scores of (b) (4) must be reviewed to determine if the failure affects the safety or effectiveness of the device. The missing datapoint for 'Shear Resistance' of the catheter was not identified during validation data review, complilation of the summary report or conclusion. The validation was approved without the deviation identified or corrected and the design validation did not meet acceptance criteria.

Additionally, the design review conducted 10/1/2013 for 'Design Validation Close Out', after the validation was completed did not identify the lacking data/deviation in the design validation.

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Observation Annotations

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

*** DATES OF INSPECTION:**
10/29/2013(Tue), 10/30/2013(Wed), 10/31/2013(Thu), 11/01/2013(Fri), 11/04/2013(Mon), 11/06/2013(Wed)

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