DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	11/29/2016-12/16/2016* FEI NUMBER 1318360

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew I. Sealfon , President & CEO

FIRM NAME	STREET ADDRESS
Repro-Med Systems, Inc.	24 Carpenter Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chester, NY 10918-1057	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 correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, your firm on 3/10/2016 issued a Corrections and Removal Notification to your customers covering multiple lots of HIgH-Flo Subcutaneous Safety Needle sets and Precision Flow Rate Tubing manufactured between 1/4/2016 and 2/26/2016, due to defects (gaps) found in the supplier's seal of sterile bag Part number (b) (4) found during post-sterilization inspection. Within your Corrections and Removal Notification dated 3/10/2016 your firm states under the Risk to Health section of the Recall Notification, "The use of affected product may possibly cause adverse health consequences, such as infection and illness". Additionally, the Notification requested, "the products to be returned to RMS for disposition."

On 3/18/2016 your firm issued an updated Corrections and Removal Notification to your customers which limited the scope of affected product to a time period of manufacturing lots from 2/8/2016 and 2/26/2016 which includes (b) (4) lots of HIgH-Flo Subcutaneous Safety Needle sets and (b) (4) lots of Precision Flow Rate Tubing.

This correction and removal was not concluded to be a reportable event to FDA and the District Recall Coordinator was not contacted to initiate a recall with FDA.

OBSERVATION 2

Procedures for design change have not been adequately established.

AMENDMENT 1

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Specifically, your firm approved Engineering Change Order Request, ECO (b) (4) on 10/12/2015, in which your firm changed the (b) (4)
Your firm failed to perform verification and/or validation activities related to this design change to ensure the design change had no negative impact on the packaging or product.

OBSERVATION 3
Procedures for corrective and preventive action have not been adequately established.

Specifically,

a) Your firm did not adequately perform verification of corrective action. CAPA (b) (4) was opened as a corrective action related to inadequate design control procedures. The CAPA states the verification acceptance criteria to close the CAPA shall include "(b) (4) .

Your firm selected the current project (b) (4) to show effectiveness of the corrective actions. Your firm is still currently in the design validation phase for this project and no completed and approved DMR exists for this project but your firm closed the CAPA on 11/16/2016. The CAPA was closed without all verification acceptance criteria defined by your firm being met.

b) Your firm's CAPA investigations appear to be inadequate:

1) Your firm discovered (b) (4) tubing sets (b) (4) from lot number (b) (4) with gaps and dips in the product's sterile bag packaging, found during post sterilization inspection. CAPA (b) (4) opened on 3/2/2016 as a result of inadequate root cause investigation by supplier when issued SCAR - CAPA (b) (4) . Your firm released (b) (4) tubing sets on 2/29/2016 from this lot prior to performing an investigation into the root cause of this non-conformity.

Additionally, after your firm determined the packaging issue affected both tubing and needle sets, the CAPA did not investigate the effects of your firm's 2016 (b) (4) Bioburden test results for the needle production area. Your firm had a contract laboratory perform bioburden testing on pre-sterilization Needle Set (b) (4)

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(b) (4) Lot (b) (4) completed on 1/22/2016. The results of this bioburden testing were higher than your firm's Action Limit for cfu. Your firm did not investigate the effects of the bioburden results on your sterile product.

2) Your firm collected a pre-sterilization sample from Needle Set (b) (4) Lot (b) (4) for bioburden testing for (b) (4) for your needle production area. This sample was collected on 1/15/2016 and test report completed by an outside laboratory on 1/22/2016. The results were determined to be higher than your Action Limit but your firm did not open a CAPA until 4/27/2016, CAPA (b) (4) after your firm had already received the results of the (b) (4) bioburden testing for the needle production area. Once the CAPA was opened your firm still did not investigate the actual effect on product manufactured during the (b) (4) including sterility related to the results being above your set action limit.

c) Your firm's current Corrective & Preventive Actions procedure SOP 8034 Rev. H dated 3/23/2016 which is the only CAPA procedure currently in use, states under section 4.6 that, "(b) (4) ." The procedure goes on to state that, "(b) (4) ."

Your firm had 3 out of (b) (4) CAPAs reviewed during this inspection covering the time period since the previous FDA inspection, in which your firm is not following its CAPA procedure for requesting extensions of CAPA. The CAPA which were still open at time of inspection, CAPA (b) (4) opened 3/2/2016, CAPA (b) (4) opened 4/27/2016 and CAPA (b) (4) opened 10/15/2015. There is no documented request for extension or justification for needing additional time or new CAPA due date documented within these three CAPA.

OBSERVATION 4

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

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Specifically, your firm has not adequately established procedures to control product that does not conform to specified requirements: including documentation of the justification for use of nonconforming product and the signature of the individual authorizing the use, the evaluation, segregation and the determination of the need for an investigation:

a) During Post-Sterilization Inspection of sterile Flow Tubing Part (b) (4) Lot (b) (4) on 2/26/2016 your firm rejected (b) (4) tubing sets for defective manufacturer's bag seal, bags came from Part Number (b) (4) RMS Lot number 109. The acceptance criteria for post-sterilization inspection follows (b) (4) . Your firm accepted (b) (4) tubing sets from this lot on 2/29/2016 for release to distribution. Prior to releasing this lot to distribution your firm did not open a Nonconforming record, internal CAPA or other record to review the rejected lot, evaluate the nonconformity, investigate or have documented justification to use as is the nonconforming lot.

b) During Post-Sterilization Inspection of Tubing Set (b) (4) Lot (b) (4) on 2/1/2016 the lot failed to meet its Acceptance Criteria of Accept on (b) and reject on (b)(. Actual sample size tested unknown only states ALL. Your firm rejected (b) (4) and the comment states "(b) (4) ". The lot was accepted and released for inventory and distribution on 2/1/2016 without documented justification for it be to used as is. Additionally, your firm did not open a non-conforming record or CAPA to evaluate, segregate or document the determination for the need for an investigation.

c) Your firm issued a SCAR on 5/5/2016 to your supplier of Part Number (b) (4) for manufacturer seal failures found during in-process inspection of Tubing Lot number (b) (4) under CAPA (b) (4) (SCAR). Your firm did not open a non-conforming material report or an internal CAPA to evaluate, segregate, investigate or document your firm's disposition of the lot of failing product. Your firm was unable to provide information related to the actual number of bags which failed in-process inspection.

d) On 8/25/2016 your firm performed incoming inspection on Product/Part # (b) (4) 12mm needle set subassembly Lot number (b) (4) which failed to meet your acceptance criteria. Four days later your firm performed incoming inspection on Part number (b) (4) 9 mm Needle Set Subassemblies under Lot number (b) (4) which also failed to meet incoming acceptance criteria on 8/29/2016. Your firm only opened one nonconformance Report, NCR (b) (4) for these two separate part numbers and incoming inspection failures.

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OBSERVATION 5

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

a) A total of 3 out of (b)(complaints reviewed received from July 2015 to the start of this inspection, were not evaluated for MDR reportability.

Complaint (b) (4) dated 8/4/2016 involving tubing snapping where it connects to the syringe with a patient involved, Complaint (b) (4) dated 8/24/2016 in which tube breaking was reported with patients involved and Complaint (b) (4) dated 8/17/2015 in which (b) patients reported extended length of time for infusion.

b)Your firm's complaint investigation is inadequate in ensuring that all information related to an event is being collected in order to fully evaluate the complaint for Reportability and to fully investigate the product malfunction. Complaints do not document attempts to gather all pertinent information regarding the event including information such as what pump, tubing, syringe or needle was being used together during infusion or in the example of Complaints (b) (4) any patient information including current status of the patients.

Additionally, within Complaint (b) (4) your firm was informed that similar malfunction events occurred (b) previous times by other end users within the month. Your firm did not attempt to collect information regarding the (b)(previous events after becoming aware.

c) Your firm's complaint investigation was inadequate for Complaint (b) (4) . Your firm received information related to (b) (4) patients complaining about tubing malfunctions including one event where a tube snapped where it connects to the syringe. The tubing lot numbers Product (b) (4) Lot (b) (4) were provided but your firm did not review the DHRs as part of the investigation into the malfunction.

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d) Within 3 out of the (b)(complaints reviewed received from July 2015 to the start of this inspection, your firm filed multiple patient involved events within one complaint file. Complaint (b) (4) ((b)(different patients and events), (b) (4) ((b)(different patient and events), and (b) (4) (b) (4 different patients and events). Your firm did not have separate complaint files to allow for full investigation of each patient event and no documentation showing each complaint event was reviewed for MDR reportability.

OBSERVATION 6

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

Specifically, your firm reworked manufacturing lots of needles and tubes from in-house inventory or returned to your firm from customers from the Correction and Removal Notification lots identified in the March 18, 2016 updated notification by re-labeling the needles and tubes with a clear sticker with a (b) (4) to be added over the original lot number. Your firm could not provide documentation showing reevaluation activities after relabeling of the product or how many units or which manufacturing lots were reworked, accepted and released back into distribution.

This rework is not documented within DHRs, CAPA or any other documentation your firm could provide.

OBSERVATION 7

Design verification does not confirm that design output meets design input requirements.

Specifically, your firm performed testing under Test Report (b) (4) to determine the number of cycles a FreedomEdge System can be used before repair or replacement of the device spring. Your firm used a sample size of (b) (4) without providing rationale for only testing (b) (4) rather than a greater number of pumps.

OBSERVATION 8

Records of acceptable suppliers have not been adequately established.

Specifically, your firm's manufacturer of Part number (b) (4) bag located in (b) (4) is not included within your approved supplier list.

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Additionally, your firm could not provide records of supplier qualification and evaluation for the (b) (4) location of this supplier following your External Supplier Qualification & Evaluation SOP 8008 Rev. B procedure.

Annotations to Observations

Observation 1: Not annotated
Observation 2: Not annotated
Observation 3: Not annotated
Observation 4: Not annotated
Observation 5: Not annotated
Observation 6: Not annotated
Observation 7: Not annotated
Observation 8: Not annotated

*DATES OF INSPECTION

11/29/2016(Tue),11/30/2016(Wed),12/01/2016(Thu),12/02/2016(Fri),12/06/2016(Tue),12/14/2016(Wed),12/16/2016(Fri)

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