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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Scott R Izyk, Investigator 12/16/2016 X Scott R Izyk Scott R Izyk Investigator Signed by: Scott R. Izyk -S	12/16/2016

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

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Chester, NY 10918-1057	Medical Device Manufacturer

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)

AMENDMENT 1

(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.

AMENDMENT 1

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

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Andrew I. Sealfon , President & CEO

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Chester, NY 10918-1057	Medical Device Manufacturer

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.

AMENDMENT 1

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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.

AMENDMENT 1

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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.

AMENDMENT 1

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Andrew I. Sealfon , President & CEO

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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)

AMENDMENT 1

	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE	Scott R Izyk, Investigator	12/16/2016 X Scott R Izyk Scott R Izyk Investigator Signed by: Scott R. Izyk -S	12/16/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	10/21/2016-11/4/2016* FEI NUMBER 3009384112

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Da Young Kim , Chief Executive Officer

FIRM NAME	STREET ADDRESS
The See Clear Company	4995 Buford Hwy Ste 102
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Norcross, GA 30071-2721	Specification Developer

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Risk analysis is inadequate and is incomplete.

Specifically, sections of your firm's Risk Management Report, KSG-RMR-01 (Rev. 0) are inconsistent with the design of your device:

- Section C.2.8, number 4 states [redacted]" and section C.2.20 states, "[redacted]". Your firm has provided data for a shelf life of [redacted] and has not provided data for a shelf life of [redacted].
- In section C 2.27-"[redacted] Your firm stated that the contact lenses require a prescription from a healthcare professional, sold only to optical stores, and are not sold directly to the end user.
- In your risk analysis, foreseeable risk "Existence of microbe that cause infection by improper sterilization" was assigned a frequency of [redacted] and severity of [redacted] and a level of [redacted]. The level of [redacted] falls [redacted] where according to the risk analysis "cannot be serious and risk reduction is not required." Your firm was unable to justify why the level of [redacted] was established in the risk analysis.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sayeeda Hdabe, Investigator Babatunde D Babalola, Investigator Karen L Anderson, Investigator X Babatunde D Babalola	11/4/2016

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	10/21/2016-11/4/2016*
	FEI NUMBER 3009384112

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Da Young Kim , Chief Executive Officer	
FIRM NAME The See Clear Company	STREET ADDRESS 4995 Buford Hwy Ste 102
CITY, STATE, ZIP CODE, COUNTRY Norcross, GA 30071-2721	TYPE ESTABLISHMENT INSPECTED Specification Developer

- In addition, the section Declaration of Conformity of Risk Management System does not include the signature and date of the individual who prepared the risk analysis and the individuals who reviewed the risk analysis.

OBSERVATION 2

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

Specifically, your Untitled (CAPA) procedure, QP90, does not include verifying or validating the corrective and preventive action, and implementing and recording changes in the methods and procedures.

OBSERVATION 3

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

Specifically, your firm does not have an adequately established procedure for receiving, reviewing, and evaluating complaints to determine when an investigation necessary. Additionally, your firm's complaint procedure does not contain the handling and maintaining of complaint files.

OBSERVATION 4

Procedures for acceptance of incoming product have not been established.

Specifically, your firm does not have an established procedure for acceptance of incoming product (contact lenses). In addition, your firm does not document acceptance and rejection of incoming product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sayeeda Hdabe, Investigator Babatunde D Babalola, Investigator Karen L Anderson, Investigator	X Babatunde D Babalola Babatunde D Babalola Investigator Signed by: Babatunde D. Babalola -S-	11/4/2016

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OBSERVATION 5

Distribution records were not maintained.

Specifically, your firm was unable to provide an established procedure for control and distribution of finished devices. Your firm was unable to provide distribution records which include or refer to the location of: (1) The name and address of the initial consignee; (2) The identification and quantity of devices shipped; (3) The date shipped; and (4) Any control number(s) used.

OBSERVATION 6

The type and extent of control to be exercised over contractors was not clearly defined.

Specifically, your firm was unable to provide a quality agreement that outlines the roles and responsibilities between your firm and your contract manufacturer. In addition, your firm has not adequately documented monitoring of your contract manufacturer.

OBSERVATION 7

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

Specifically, your Untitled (Non-conforming product) procedure, QP86, does not include documentation, evaluation, segregation, and disposition of nonconforming product.

OBSERVATION 8

The documentation of approval of documents does not include the document approval date and the signature of the approving official.

Specifically, the procedure listed below does not include the approval date and signature of the approving official:

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Da Young Kim , Chief Executive Officer

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Management Review QP20
Management Review QP23
Internal Audit Procedure QP-8-2, Rev 0
Internal Quality Audit Procedure R007
Training Competency QP26
Personnel QP25
Untitled Procedure, QP86
Medical Device Reporting, QP0317
Purchasing Controls, QP50
Untitled Procedure, QP-186, Rev. 0
Recall Advisory Notices, QP80

OBSERVATION 9
A device history record has not been adequately maintained.

Specifically, your firm was unable to provide a complete Device History Record for the entire quantity of Lot No. E28Hjwf.

OBSERVATION 10
The dates of quality audits have not been documented.

Specifically, your firm was unable to provide the dates of the quality audits for 2014, 2015, and 2016.

OBSERVATION 11
Management with executive responsibility has not reviewed the suitability and effectiveness of the quality system at defined intervals.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sayeeda Hdabe, Investigator Babatunde D Babalola, Investigator Karen L Anderson, Investigator 11/4/2016 X Babatunde D Babalola Babatunde D Babalola Investigator Signed by: Babatunde D Babalola S.	11/4/2016

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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Da Young Kim , Chief Executive Officer

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Norcross, GA 30071-2721	Specification Developer

Specifically, your firm was unable to provide the dates and results for the quality system reviews for 2014 and 2015.

OBSERVATION 12
Personnel training is not documented.

Specifically, your firm was unable to provide documented training records for the employees.

Annotations to Observations

Observation 1:	Promised to correct
Observation 2:	Promised to correct
Observation 3:	Promised to correct
Observation 4:	Promised to correct
Observation 5:	Promised to correct
Observation 6:	Promised to correct
Observation 7:	Promised to correct
Observation 8:	Promised to correct
Observation 9:	Promised to correct
Observation 10:	Promised to correct
Observation 11:	Promised to correct
Observation 12:	Promised to correct

***DATES OF INSPECTION**
10/21/2016(Fri),10/24/2016(Mon),10/26/2016(Wed),10/27/2016(Thu),10/31/2016(Mon),11/01/2016(Tue),11/04/2016(Fri)

11/4/2016

X Sayeeda Hdabe
Sayeeda Hdabe
Investigator
Signed by: Sayeeda Hdabe -5

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sayeeda Hdabe, Investigator Babatunde D Babalola, Investigator Karen L Anderson, Investigator 11/4/2016 X Babatunde D Babalola Babatunde D Babalola Investigator Signed by: Babatunde D Babalola -5	11/4/2016

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)587-7500 Fax:(781)587-7556	2/6/2017-2/7/2017
	FEI NUMBER 3005144609

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Russell A. Nadeau , Chief Operating Officer

FIRM NAME	STREET ADDRESS
Eptam Plastics, LLC	2 Riverside Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Northfield, NH 03276-4407	Medical Device Contract Manufacturer

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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

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

Specifically,
a) complaint files with the evaluations, investigations, and complaint determinations have not been maintained.

b) the Nonconformance Procedure - QCP-11:00-N, which addresses complaint handling, does not adequately define the process for reviewing, evaluating, and investigating complaints.

Annotations to Observations

Observation 1: Reported corrected, not verified

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Abby E Pelletier, Investigator	2/7/2017 X Abby E Pelletier Abby E Pelletier Investigator Signed by: Abby E. Pelletier -S	DATE ISSUED 2/7/2017

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."