DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969	7/10/2018-8/22/2018* FEI NUMBER 3004641714

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ann Prewett, President

FIRM NAME	STREET ADDRESS
Replication Medical, Inc.	7 Deerpark Dr Ste C5
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Monmouth Junction, NJ 08852-1921	U.S. Manufacturer of Export only devices

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 device master record has not been maintained.

Specifically, during the inspection, you were unable to provide an approved Device Master Record for your GelFix device for review.

OBSERVATION 2

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

Specifically,

A. For CAPA-044, no water sample was tested for TOC (Total Organic Content). CAPA-044 was initiated on Jun 21, 2016 due to a (b) (4)-micron filter that had been installed improperly on the water system. This resulted in a broken water hose flooding the facility. The corrective and preventive action plan states that after cleaning up the system and replacing the (b) (4)-micron filter correctly a water sample would be tested for TOC (Total Organic Content) to assure it was within specification. You failed to perform the test for TOC.

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B. An effective check is not included in CAPA-043, which was initiated on July 19, 2016 for an internal audit observation. A time extension was requested to complete the CAPA. No documentation was available to show that the effectiveness check was completed for this CAPA.

C.

1. CAPA- 047 was closed before implementing the QC check, QC-052, Rev 4, a final QC check prior to packaging the GelFix device in foil. The CAPA- 047 was opened on April 05, 2017 and closed on 18 February 2018. This CAPA was initiated because a suture loop on the GelFix device was too small in 3 units of Size 10. The QC-052, "Gelfix and GelPerc Interspinous Process Device IPC Inspection", Rev 4, Effective date is July 25, 2018.

2. Additionally, for CAPA -047, a CAPA Summary Report states that a (b) (4) to (b) (4) would be implemented as part of the corrective action to the CAPA. However, this procedure, "GelFix and GelPerc Interspinous Process Device Production", Document # MP 051, Rev 14, had already been in place as of October 20, 2016. Additionally, several DHRs for GelFix did not document nor record that the (b) (4) using the (b) (4) tool was used.

OBSERVATION 3

The device history record does not demonstrate that the device was manufactured in accordance with the device master record.

Specifically,

A. The portion of the GelFix device history record representing the "(b) (4) (b) (4) Document # DHR-001, section 6.6.4, deviated from the specification provided in the batch record. The specification is (b) (4) with respect RPM adjustment (motor speed set (b) (4

(b) (4) For batch number HP80-194Q, the motor speed was readjusted after 10 min as noted in section MP-001 6.6.4.

B. PSI level is not documented in the (b) (4) ", Document # DHR-006. For example, batch numbers HP80-194Q, HP80-298Q and HP80-141S. Per the procedure (b) (4) ", Document # MP-006, Rev 01, section 6.1.5 states that the pressure of approximately (b) (4) is required to be used in the (b) (4) step. In addition, for batch number HP-298Q, final (b) (4) (b) (4) section MP-001 6.1.5 and (b) (4) , section MP-001 6.1.4, are not documented.

C. Batch IPD-218QB, the portion representing the "GelFix and GelPerc Interspinous Process Device Production" Document # DHR-051, did not meet the temperature requirement of (b) (4) Celsius. It is recorded as 40 Celsius in section MP-052 6.4 noting drying process. Furthermore, no rationale was provided for missing one of the GelFix units. Initially (b) (4) implants/units were manufactured and at the start of the drying process, however (b) (4) implants were reconciled.

D. Several device history records, section MP-051 6.4, indicate that the drying time was exceeded. Per procedure, "GelFix and GelPerc Interspinous Process Device Production, Document # MP-051, Rev 14, section 6.4.1.3 states (b) (4) Celsius (b) (4) to dry the implants to a target of (b) (4) % the (b) (4) (b) (4) which is noted to take approximately (b) (4) depending on implant size. The following batches exceeded the drying time.

i. Batch number IPD-309QC, the GelFix implants were placed in the (b) (4) on 10 November 2016 at 5:39 pm and it was removed on (b) (4) .

ii. Batch number IPD -145 SA, the GelFix implants were placed in the drying oven on 31 May 2018 at 2:31 pm and it was removed on (b) (4)

iii. Batch number IPD -152 SA, the GelFix implants were placed in the drying oven on 06 June 2018 at 3:53 pm and it was removed on (b) (4)

b. Device History record for GelFix, lot numbers IPD-218QB, IPD-309QC, and IPD-145SA do not include documentation of representative labeling noting "For Export Only" as part of the batch record.

OBSERVATION 4
Production processes were not controlled to ensure that a device conforms to its specifications.

Specifically, A procedure for replacing the filter in the water system was not developed. For example, CAPA-042 was initiated on May 16, 2016 due to High TOC (total organic content) in the water sample due to a (b) (4) micron filter have been placed in the reverse direction in the housing. There is no procedure in place for replacing the filter in the water system.

OBSERVATION 5
Procedures for corrective and preventive action have not been adequately established.

Specifically, Complaint trends were not routinely conducted every (b) (4). The complaint handling procedure, SOP-041, Rev 05, Effective date 20 July 2016, section 6.2.21 states that the complaints trends are conducted as necessary but at a minimum (b) (4).

OBSERVATION 6
Documents were not reviewed and not approved by designated individual(s) prior to issuance .

Specifically, instructions referred to as "NeuFx Lumbar Surgical Procedure" device was updated to state the following "Note: Only one or two turns is necessary to secure holder". This change did not go

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through the document change request (DCR) process. Per the Quality System Manual, section 4.3, states document control and document change control are applicable for all documents as described in the quality system manual and procedure book. Table 1 in the quality system manual, includes device labeling.

***DATES OF INSPECTION**

7/10/2018(Tue), 7/11/2018(Wed), 7/12/2018(Thu), 7/25/2018(Wed), 7/26/2018(Thu), 8/03/2018(Fri), 8/20/2018(Mon), 8/22/2018(Wed)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Corrected and verified

Observation 6: Not annotated

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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."