DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772	1/30/2019-1/31/2019
	FEI NUMBER 3010128811

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Barbara L. Rivers, Quality and Compliance Manager

FIRM NAME	STREET ADDRESS
Full Range Rehab LLC	4722 Interstate Dr Ste K
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cincinnati, OH 45246-1145	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

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically,

You did not report your complaint received 10/19/2017 including an injury to the patient as an MDR within 30 calendar days according to your procedure C-1013 "Safe Medical Device Act" Revision: 4, Date: 10/16/2017. It was not reported until 02/03/2018, 107 days later. Furthermore, this is your only documented complaint and MDR since the previous inspection ending 03/15/2017.

OBSERVATION 2

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

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EMPLOYEE(S) SIGNATURE
Teresa K Kastner, Investigator

X Teresa K Kastner
Investigator
Signed By: Teresa K. Kastner -S
Date Signed: 01-31-2019 13:16:37

DATE ISSUED
1/31/2019

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Specifically,

You did not document any corrections from the previous inspections eight observations within the CAPA system. Furthermore, five of the eight previous observations corrections, including CAPA, were inadequate in that there are multiple repeat observations. For example, you still have not established an internal audit procedure or conducted internal audits. Additionally, section 3 of your CAPA procedure C-1017 "CAPA (Corrective and Preventive Actions)" Revision: 3, Date: 10/16/2017 does not include external audit findings as an example of when a CAPA would be requested.

This is a repeat Observation.

OBSERVATION 3

Procedures for quality audits have not been established.

Specifically,

On 01/30/2019, the Quality and Compliance Manager stated the firm does not currently have a procedure addressing auditing their quality system, nor has the firm conducted quality audits.

This is a repeat Observation.

OBSERVATION 4

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

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Specifically,

The firm's complaint handling procedure, C-1001 "Client Complaint Resolution" Revision: 3, Date: 9/18/17, does not adequately define all customer complaints. For example, the procedure does not call out documenting notifications of the firm's device not functioning properly as a complaint. The Quality and Compliance Manager stated repairs of the firm's devices, such as replacing a control unit that is no longer working, are not routinely recorded or documented. The Quality and Compliance Manager stated the firm did not record any repairs as complaints.

This is a repeat Observation.

OBSERVATION 5

Procedures for device history records have not been adequately established.

Specifically,

According to the Quality and Compliance Manager, there is no procedure defining the documentation, content and storage requirements for DHRs. DHRs are electronically generated and stored in a custom application, (b) (4) , pilot implemented (b) (4) that according to the Quality and Compliance Manager has not been validated. Additionally, the DHRs do not include the labeling for the device. Prior to the implementation of the application, DHRs for the devices were not maintained.

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This is a repeat Observation.

OBSERVATION 6

A device master record has not been adequately maintained.

Specifically,

Your device master record does not include or refer to the location of product labeling including the instructions for use. Furthermore, it does not include the procedures for label location or the repair and troubleshooting of the units. According to the Quality and Compliance Manager, there are no procedures specifically addressing the control, generation and placement of labels and for the troubleshooting of the units. She stated that they are using the manufacturing procedure, C-1016 "Receiving Acceptance" Revision: 1, Date: 10/04/2017, as the repair procedure and there is no other procedure defining the troubleshooting and repairing of the devices.

This is a repeat Observation.

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Annotations to Observations

Observation 1: Annotation Intentionally Left Blank

Observation 2: Annotation Intentionally Left Blank

Observation 3: Annotation Intentionally Left Blank

Observation 4: Annotation Intentionally Left Blank

Observation 5: Annotation Intentionally Left Blank

Observation 6: Annotation Intentionally Left Blank

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