DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	6/12/2017-6/14/2017
	FEI NUMBER 3003395204

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Timothy J. Kelly , Executive Vice President

FIRM NAME	STREET ADDRESS
Biolife, LLC	8163 25th Ct E
CITY, STATE, ZIP CODE, COUNTRY Sarasota, FL 34243-2800	TYPE ESTABLISHMENT INSPECTED 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

Procedures for design change have not been adequately established.

Specifically,

Your firm conducted a design change to the container of your Over-the-Counter hemostatic wound dressing powder from a (b) (4) Your design change documentation shows the design change was approved for Production Release on 9/14/16. Shipment documentation provided during the inspection show that product in (b) (4) were shipped in January 2016.

OBSERVATION 2

Written MDR procedures have not been implemented.

Specifically,

Your firm has not reported to the US Food and Drug Administration information from customer complaints that appear to meet the definition of Adverse Events for your topical hydrophilic dressing products for temporary bleeding control associated with minor wounds including:

a) Feedback / Complaint ID 1090, with entry date 12/29/16, referencing wound infections, doctor

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visits, and antibiotic treatment.

b) Feedback / Complaint ID 1097, with entry date 1/20/17, referencing a pressure ulcer.
c) Feedback / Complaint ID 1086, with entry date 12/9/16, referencing skin breakdown following use of your wound dressing hemostatic disc in conjunction with non-stretching adhesive skin closure devices. Feedback / Complaint ID 1086 references a total of three (3) similar occurrences of skin reactions. Your firm has only submitted MDR Report # 1066421-2017-00001, with report date 12/8/16, associated with one of the occurrences.

OBSERVATION 3
Complaint files are not adequately maintained.

Specifically,

Your firm's procedure MOP 14-02.11, Customer Feedback / Customer Complaints, Rev 11, Effective Date 10/14/16, provides for complaint investigations; and the processing of reportable events in accordance with QOP 14-04.13, Recalls, Advisory Notices and Vigilance, Rev 13, Effective Date 2/12/16 which includes an MDR Checklist for the determination of reportable events.

a) The record for Feedback / Complaint ID 1097, with entry date 1/20/17, referencing pressure ulcer does not demonstrate an adequate investigation was conducted to determine whether an Adverse Event had occurred.
b) An MDR checklist was not utilized to document justification that an MDR was not required for Feedback / Complaint ID 1097, with entry date 1/20/17 referencing pressure ulcer or Feedback / Complaint ID 1090, with entry date 12/29/16 referencing wound infections, doctor visits, and antibiotic treatment .
c) The records for Feedback / Complaint ID 1097, with entry date 1/20/17 referencing pressure ulcer, and Feedback / Complaint ID 1086, with entry date 12/9/16 referencing skin breakdown did not include relevant details of event description and investigation follow-up respectively.

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OBSERVATION 4

Procedures for corrective and preventive action have not been established.

Specifically,

Your firm did not take appropriate actions to prevent the recurrence of quality problems. CAPA CA16-03, initiated 3/21/16 for out of tolerance results during calibration of equipment including balance, with equipment (b) (4) , used to weigh bottles of hemostatic wound dressing powder in production, states the balance has been out of tolerance for a fourth consecutive year.

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct
Observation 3: Promised to correct
Observation 4: Promised to correct

AMENDMENT 1

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