DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	8/11/2017-8/15/2017*
	FEI NUMBER 3009182435

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Byron G. Zahler , President

FIRM NAME	STREET ADDRESS
BZ Medical, Inc.	6611 SW Burlingame Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Portland, OR 97239-2639	Medical Device Specifications Developer

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

Written MDR procedures have not been developed.

Specifically,

Your firm's procedure 820.198-A Complaint File, identified as the procedure referencing submission of MDR events, does not include provisions for:

a. A standardized review process for determining when an event meets the requirements for submission as an MDR, including evaluating whether information you become aware of reasonably suggests that a device you market may have caused or contributed to a death or serious injury, or has malfunctioned and this device or a similar device you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
b. Timely transmission of complete medical device reports to the FDA, including processes for:
   i. Submission of reports no later than 30 calendar days after the day you become aware of an MDR reportable event.
   ii. Submission of reports within 5 working days when an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, or upon written request for such a report by the FDA.
   iii. Submission of supplemental or follow-up reports within 30 calendar days of receiving required information.

AMENDMENT 1

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	James D Hildreth, Investigator	X James D Hildreth Investigator Signed By: James D. Hildreth -S Date Signed: 8/15/2017	8/15/2017

iv. Electronic submission of reports.

c. Documentation and recordkeeping requirements for information evaluated to determine if an event was reportable, all MDRs and information submitted to the FDA, and systems that ensure access to information by the FDA.

OBSERVATION 2

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically,

Your firm's procedure 820.50-A Purchasing requires your firm to evaluate supplier performance (b) (4) against criteria including meeting specifications, on time delivery, correct quantity, quality and condition, and competitive pricing. Review of two suppliers for the Ca+lgaeSeal device found the following:

a. Since 12/2013, your firm documented only one (1) evaluation of the subcontractor manufacturing (b) (4) from 2013 to 2016, dated 12/30/2015. The previous documented evaluation of this supplier was dated 03/14/2011.

b. Since 12/2013, your firm has not documented the evaluation of the supplier providing (b) (4) (b) (4) to the device package.

OBSERVATION 3

Quality audits were not performed at defined intervals to determine whether the quality system activities and results comply with quality system procedures.

Specifically,

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Your firm has not conducted an internal quality audit within the past (b) (4) years according to your firm's procedure 820.22-B Quality Audit, section 5.1. Your firm's last documented internal quality audit was conducted between 05/28/2012 and 06/01/2012.

OBSERVATION 4

Procedures for device history records have not been adequately established.

Specifically,

Your firm's procedure 820.184-A Device History Record does not include a requirement for the documentation of primary product labeling in the Device History Record (DHR). Review of 18 DHRs found that all 18 did not include or reference the location of the primary device label or labeling for the Ca+lgaeSeal device, including the following:

~~e.~~ **a.** The pouch label applied to each sealed pouch, number LblCaS-02C (12/10) used from 12/2013 to 06/2016 and number LblCaS-02F (06/16) used after 06/2016.

~~d.~~ **b.** The Directions for Use provided in each box of 10 devices, number LblCaS-01B (06/10).

~~e.~~ **c.** The box labeling for the box into which ten (1) devices are packed, number LblCaS-04C (12/10).

Annotations to Observations

Observation 1:	Promised to correct
Observation 2:	Promised to correct
Observation 3:	Promised to correct
Observation 4:	Corrected and verified

*DATES OF INSPECTION

8/11/2017(Fri),8/15/2017(Tue)

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