DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	10/2/2017-10/16/2017* FEI NUMBER 1000220733

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

David J. Kunz, Senior Vice President of Global Quality & Regulatory Affairs

FIRM NAME	STREET ADDRESS
Zimmer Biomet, Inc.	1800 W Center St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Warsaw, IN 46580-2304	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 WE OBSERVED:

OBSERVATION 1

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

Note: This is a repeat from FDA inspection conducted from 7/6/11 to 7/22/11 (Obs. 1), 4/16/12 to 5/21/12 (Obs. 2), 5/6/13 to 6/20/13 (Obs. 1), 4/21/14 to 5/28/14 (Obs. 2) and 10/19/2015 to 11/20/15 (Obs. 2)

Specifically,

Your firm has not identified the appropriate scope needed to correct and prevent the recurrence of nonconforming product per Corrective & Preventive Action Process SOP 13.401.

Per the Corrective & Preventive Action Process SOP 13.401 a Correction is defined as "action to eliminate a detected nonconformity. Examples include *** containment of an existing nonconformity." On 11/24/2015, your firm initiated CAPA00001509 to address the recurrence of the usage of nonconforming Class II Hip and Class II/III Knee implants found adhered with Low Density Polyethylene (LDPE) bag in which they are held. The correction pertaining to containment of the existing nonconformity was the initiation of a recall, ZFA 2015-180 which was terminated on 05/26/2017.

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On 06/27/2017 your firm received complaint CMP-0303384 alleging that a surgeon opened a femoral implant and found parts of the plastic bag sticking to the implant. The surgeon then cleaned the plastic from the implant and implanted the device in the patient. The investigation into the complaint concluded on 08/24/2017. The investigation details for this complaint concluded that the plastic bag sticking on the implant was the "old style poly bag (b) (4) . The complaint also references CP154 which identified the corrective action of replacing the "old LDPE bag" with a new LDPE bag for implant packaging going forward. CAPA 1509 also reference CP154 regarding the "sticky bag issue".

Complaint CMP-0303384 documents the item number of the nonconforming implant as (b) (4) . This part number was not included in the scope of the CAPA 1509 containment action ZFA 2015-180. The scope of the containment action was not sufficient to correct and prevent recurrence of the nonconformity.

OBSERVATION 2

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

Specifically,

a. Product found with contamination during inspections at the final clean operation are not documented using a nonconformance report.

   Per Nonconformance Process SOP 13.301 if a nonconformity is identified as "Special Cause Nonconformance" your firm will initiate an NCR (nonconformance report). Nonconformances identified as special cause during (b) (4) performed in (b) (4) are defined in (b) (4) , also known as a JDE Visual Aid; this visual aid identifies Contamination as "Special Cause" and states "NCR required". Your firm's definition of contamination is found in Visible Discoloration, Foreign/Fibrous Material and Contamination SOP 13.143.IN.1 which states that contamination refers to (b) (4) .

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The procedures for documentation of "Special Cause" nonconformances in a Nonconformance Report was not followed. For example,

1. During the inspection 11 records were sampled from a list of your firm's scrap records; 1 of the 11 records documented that the cause for scrap was "Contamination". However, no corresponding NCR was located.

2. During a tour of the (b) (4) operations, an operator interviewed stated that if visible debris was identified on a product that has been processed through (b) (4), he/she would clean the visible debris (b) (4), he/she would not initiate an NCR to document the contamination. The lack of NCR documentation does not follow your firm's NCR procedures.

b. A nonconformity not identified as Common Cause or Special Cause Nonconformance was not documented using a nonconformance report per existing procedures.

Per Nonconformance Process SOP 13.301 if a "Nonconformity not identified as Common Cause or Special Cause in SOP 12.811 Indexes and Visual Aids" is found during an inspection process your firm will initiate an NCR. Nonconformances identified during (b) (4) performed in (b) (4) are all defined in (b) (4), also known as a JDE Visual Aid.

In 1 of 11 records sampled from a list of your firm's scrap records, your firm documented on a Common Cause Rework Form a nonconformance of "(b) (4)" with the rationale of (b) (4). This nonconformance was dispositioned as "Scrap". The nonconformance caused by a component of a device (b) (4) (b) (4) is not described in (b) (4) Per Nonconformance Process SOP 13.301, an NCR should have been initiated to document this nonconformance. However, no corresponding NCR was located.

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OBSERVATION 3

Device packaging and/or shipping containers are not designed and constructed to protect the device from alteration or damage during processing, storage, handling, and distribution.

Note: This is a repeat from FDA inspection conducted from 10/19/2015 to 11/20/15 (Obs. 6)

Specifically, your firm's Packaging Development Conditioning and Testing Guidance procedure, ZWI 31.110 Rev. 16 effective 15-Feb-2017, does not provide adequate assurance that all packaging systems will provide physical protection and maintain the integrity of the sterile barrier system through normally anticipated hazards associated with shipping. Under this procedure, the applications of climatic conditioning for packaging systems used to support new product development projects or design changes are not the same as those required for legacy packaging configurations. For example,

Table 1: Product/Package Development Packaging Systems from Rev. 16 (based on ISTA 3A - General Simulation Performance Test Procedure):

Step	Climatic Condition	Temperature	% Relative Humidity	Exposure Time
(b) (4)				

Table 2: Legacy Packaging Configurations from Rev. 16 (based on ASTM 2825 – Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery):

Step	Climatic Condition	Temperature	% Relative	Exposure

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(b) (4)

Your firm confirmed that only one distribution channel study has included documentation of temperature and humidity for global shipping locations. Your firm confirmed that the objectives of that study were not to characterize temperature or humidity exposure during customary distribution channels. Furthermore, your firm confirmed that there was insufficient data points, seasonal consideration, and selection of distribution routes to draw meaningful conclusions from this temperature and humidity data. As of 10/13/2017, your firm has no additional global distribution channel characterization data to support the decision to test Legacy Packaging Configurations with less extreme climatic conditioning.

OBSERVATION 4

Procedures for monitoring and control of process parameters for a validated process have not been adequately established.

Specifically, Issue Evaluations (IE's) were not opened when statistical process control (SPC) control charts showed that process monitoring data had drifted outside of established control limits. Per the Sampling and

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Monitoring Plan Establishment and Maintenance procedure, GSOP 42.008.IN.18 Rev. 2, (b) (4) " For example, review of SPC data for (b) (4)) process parameters of Metal Backed Patellas from 02/01/2016 to 09/12/2017 showed that control limits were exceeded:

- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)

No IE's were opened for these instances of exceeded control limits. Your firm manufactures (b) (4) different products that undergo the (b) (4) process.

OBSERVATION 5

Software used as part of the quality system has not been adequately validated for its intended use according to an established protocol.

Specifically, your firm's validation of the software used to determine the scope of a quality hold was not performed per Computer Systems Validation Process IT2.003.

Computer Systems Validation Process IT2.003 references Validation of Software for Regulated Processes AAMI TIR36: 2007. The software validation for (b) (4) and (b) (4) do not conform to requirements documented in AAMI TIR36. For example,

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c. Per AAMI TIR36, software validation should include "Data verification" which refers to "activities completed to confirm the correctness of data." However, the data output from the (b) (4) was not documented to have been verified against a known value for correctness.

d. Per AAMI TIR36, software validation should include "Robustness testing (stress testing)". "Robustness testing should demonstrate that a software product behaves correctly when given unexpected, invalid inputs." "Stress testing is testing conducted to evaluate a system or component at or beyond the limits of its specified requirements." The robustness or stress testing was not included in the (b) (4) validations in the following ways.

1. The (b) (4) and (b) (4) are used routinely to create quality holds for products in a (b) (4) of (b) (4). However, only a (b) (4) of (b) (4) was tested during the validation.

2. Per your firm's subject matter expert for the (b) (4) and (b) (4) validations the (b) (4) can generate errors when used to query large date or data ranges. However, these error conditions were not tested during the validation.

   Additionally, per the (b) (4) the possible status of a search using (b) (4) can be "error". The procedure does not provide instructions for how to troubleshoot that error.

The (b) (4) and (b) (4) have been used as part of the (b) (4) since 08/17/2016; (b) (4) quality holds have been executed between 08/17/2016 and 10/02/2017.

OBSERVATION 6

Procedures to ensure equipment is routinely calibrated have not been adequately established.

Note: This is a repeat from FDA inspection conducted from 10/19/2015 to 11/20/15 (Obs. 5)

Specifically, your firm's calibration procedures:

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- number CP09300, "Calibration," revision numbers 2 ***, effective 13 Mar 2017 ***;
- number ZWI 43.300, "Calibration System Control," revision numbers 14 ****, effective 15-Sep-2017 ***;
- number ZWI 43.301, (b) (4) Environmental Control," revision numbers 11.1 ****, effective 27-Jul-2017 ***;
- number ZWI 43.302, "Calibration Standards," revision numbers 6.1 ****, effective 27-July 2017 ***;
- number ZWI 43.303, "Entering In/Removing From Service, Measurement And Test Equipment," revision numbers 11 ****, effective 15-Sep-2017 ***;
- number ZWI.304, "Calibration Procedures," revision numbers 17****, effective 29-Aug-2017 ****;
- ZWI 43.305, "Calibration Intervals," revision numbers 16 ****, effective 19-Sep-2017 ****;
- ZWI 43.306, "Calibration Not Required Justification," revision numbers 8.1 ****, effective 27-Jul-2017 ****;
- ZWI 43.307, "Supplier Calibration Guidelines," revision number 13 ***, effective date 28-Sep-2017 ****;
- ZWI 43.308, "Calibration Due Notification," revision numbers 11 ***, effective date 15-Sep-2017 ****;
- ZWI 43.410, "Calibration Label Use Guidelines," revision numbers 8.1 ****, effective date 27-Jul-2017 ****;
- ZWI 43.311, "Out of Tolerance Equipment," revision numbers 24.1 ****, effective date 27-Jul-2017 ***; and

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- ZWI 43.312, "(b) (4) Hold Tag," revision numbers 5.1 ****, effective date 27-Jul-2017 ****

do not ensure that all pieces of equipment are calibrated as required. For example,

One (1) out of eleven (11) calibration records reviewed did not have calibration completed per you firm's set calibration intervals. (b) (4) number (b) (4) a (b) (4), is required to be calibrated every (b) (4). The last calibration for this piece of equipment was conducted on 21 Oct 2016. Your firm's system has the recalibration date for this piece of equipment to be December 31, 2017.

OBSERVATION 7

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

Note: This is a repeat from FDA inspection conducted from 10/19/2015 to 11/20/15 (Obs. 9)

Specifically, your firm's complaint handling procedures:

- CP04000, "Complaint Handling," revision numbers 1-5, effective Sept 21, 2015-19 June 2017;
- CP04006, "Complaint Investigation," (previously titled "Product Evaluation,") revision numbers 1-5, effective Sep 21 2015, May 3, 2016, 10 Jan 2017, 13 Mar 2017, and 19 June 2017;
- CP04009, "Creation of a Reportability Guidance Document (RGD)," revision number 1, effective date 13 Mar 2017;
- CP04011, "Complaint Management," revision number 1, effective date 19 June 2017;
- CP04012, "Complaint Intake," revision number 1, effective date 19 June 2017;

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- WI040002, "Constructing Regulatory Progress Report from (b) (4) revision number 1, effective date 01-Sep-2017;
- WI040004, "ZMR Complaints," revision number 1, effective date 01-Sep-2017;
- WI040005, "Decontamination Process for Complaint Product," revision number 1, effective date 01-Sep-2017;
- WI 04006, "Complaint Investigation," revision number 1, effective date 01-Sep-2017;
- WI040011, "Complaint Management," revision number 1, effective 01-Sep-2017; and
- WI040012, "Complaint Intake," revision number 1, effective 01-Sep-2017;

do not contain a mechanism for your employees to determine when a complaint received by your firm will be made "void" or "not a complaint". Furthermore, CMP-0229905, which was received on Jun 23, 2016, for instability of a knee, was considered not a complaint by your firm. Your firm investigated and determined that the complaint was not device related. The status of the complaint was changed the status to "Not a Complaint" on or around July 22, 2016.

OBSERVATION 8

Written MDR procedures have not been implemented.

Note: This is a repeat from FDA inspection conducted from 10/19/2015 to 11/20/15 (Obs. 10)

Specifically, procedure numbers

- CP04000, "Complaint Handling," revision numbers 1-5, effective Sept 21, 2015-19 June 2017;
- CP04001, "Device Reporting," revision numbers 1-5, effective Sep21, 2015-23-Aug-2017;
- CP04002, "MDR and MEDDEV Reports Guidance," revision 1, effective 23-Aug-2017; and
- CP04003, "Reportability Guidance Document (RGD) Process," revision 1, effective 13 Mar 2017

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do not ensure that MDRs for serious injuries are reported as required. For example, for CAPA number 1467, a retrospective review for MDRs was conducted. A Retrospective Summary Report (RSR) was requested and approved covering only malfunction event covering devices under Product Codes HWA-Impactor, LXH-Orthopedic Manual Surgical Instrument, HTW-Bit Drill, and HWT-Template. Your firm filed both the malfunction and serious injury MDRs under the RSR. This includes the following numbers of serious injury reports:

Product Code	# of Serious Injury
LXH	32
HTW	18
HWT	4
HWA	1

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**

10/02/2017(Mon), 10/03/2017(Tue), 10/04/2017(Wed), 10/05/2017(Thu), 10/06/2017(Fri), 10/10/2017(Tue), 10/11/2017(Wed), 10/12/2017(Thu), 10/13/2017(Fri), 10/16/2017(Mon)

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