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	4/9/2018-4/24/2018* FEI NUMBER 1825034

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

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

FIRM NAME	STREET ADDRESS
Zimmer Biomet, Inc.	56 E Bell Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Warsaw, IN 46582	Medical Device

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.

This is a repeat observation from the FDA inspection dated 9/12/2016 to 11/22/2016.

Specifically,

A. Corrective actions were not effective in preventing recurrence of bacterial endotoxin test (BET) failures in polyethylene devices.

CAPA #CA-03241 was initiated on 1/25/2017 after two polyethylene devices cleaned in work center (b) (4) failed bacterial endotoxin testing (BET). A "(b) (4) " in the work center was identified as the root cause of the failures and was removed from service on 1/23/2017. Your firm conducted a recall of all polyethylene product cleaned in the work center between 12/12/2016 and 1/20/2017.

Subsequently, another polyethylene device cleaned in work center (b) (4) on 2/27/2017 failed BET (item

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	Thomas A Peter, Investigator Christina L Bigham, Investigator Benjamin J Dastoli, Investigator Rosanna M Goodrich, Investigator	X Thomas A Peter Investigator Signed By: Thomas A. Peter -S Date Signed: 04-24-2018 18:34:03	4/24/2018

(b) (4)). The third occurrence was added to CAPA #CA-03241 because "it was determined that the failure was consistent with the original failures identified". The CAPA attributed the root cause of the third failure to the manual nature of the cleaning operation and "if performed inadequately" can lead to failure to meet requirements.

In response to the third BET failure, HHE (Health Hazard Evaluation)/ZFA (Zimmer Field Action) #2017-109 was initiated to assess the need for additional field action. On 5/5/2017, your firm determined no field action was necessary because a study report (b) (4) ; dated 4/5/2017) demonstrated the manual cleaning operation "exceeds a 99% confidence that more than 99%" of all distributed product meets specification ((b) (4) EU/device). The study does not provide objective evidence to support this conclusion. Specifically:

i. The manual cleaning process involves operators (b) (4) in an (b) (4) and scrubbing them with a nylon brush. The validation of this process was found to be inadequate during the previous FDA inspection. Your firm also determined noncompliance with all four (4) OQ requirements and two (2) PQ requirements during a "Process Validation Assessment" approved on 7/24/2017.

   To date, the process as it existed at the time has not been adequately validated. The study report ((b) (4)) appeared to represent a performance qualification (PQ) comprising (b) (4) polyethylene device families. The study failed to demonstrate the process is consistently capable in worst-case conditions normally established during OQ (*e.g.*, (b) (4) .

ii. Your firm was unable to provide objective evidence to refute the possibility that operators manually cleaned devices more rigorously during the study than would normally be performed.

iii. Pre-established acceptance criteria were not documented in the corresponding protocol ((b) (4) "; dated 3/22/2017) because "this is an investigative study." The study report states that cleaned devices were required to "achieve a capability of at least Ppk(b) (4) This criterion was said to be met; however, your firm assumed the data was normally distributed.

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During this inspection, you re-checked the data and confirmed it was not normal and could not be transformed. As such, process capability analysis could not be performed.

iv. (b) (4) families of devices were tested during the study, of which two were cleaned using a (b) (4) automated machine wash. This process is not representative of the manual cleaning processes used at the time of the third BET failure.

v. Confidence and reliability was calculated by pooling the samples across all families tested. Recalculating the results by family yielded lower confidence and reliability than claimed in the study:

Family	Confidence	Reliability
(b) (4)		

B. Your firm's CAPA CA-3092, opened on 12/01/2016 and in action implementation phase, is not taking action commensurate with risk. CA-3092 was opened to address inadequate "process control procedures for in-process and final cleaning" and the remediation of cleaning validations. Your Engineering Manager stated this CAPA also includes any issues that may arise from the cleaning process validations.

For final cleaning processes that have yet to be validated, your firm is performing additional monitoring in accordance with SOP 28.0.1, "Process Monitoring of Final Cleaning," Revision 9. These values are then interpreted in accordance with QM 28.0, "Process Monitoring of Validated Processes," Revision 12. Additionally, the process performance indicator (Ppk) is (b) (4) for input into CAPA, though this process is not currently outlined in one of your procedures, according to your Corporate Quality Director on 04/24/2018.

These Ppks indicate not all of your cleaning processes are currently in control. For example, your (b) (4) machining group has a calculated Ppk of (b) (4) and (b) (4) for the (b) (4)

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(b) (4) residual testing from 01/28/2018 to 03/30/2018 and 12/16/2017 to 03/20/2018 respectively, which equates to a potential product percent defect of (b) (4)% and (b) (4)%. Additionally, your (b) (4) machining group has failed two validations: OQPQ-11047-001 r0 on 01/16/2017, and VP-11047-001 r1 on 02/22/2017 and has not yet been validated. Your firm currently manufactures and distributes products that are part of this product family.

Your Engineering Manager stated high results in your cleaning process monitoring data and validation testing for (b) (4)) and (b) (4)) extract is attributed to high levels of debris, due to the method of your firm's contracted testing. Your Engineering Manager also stated the cause of the debris had been determined to be the (b) (4) from your firm's (b) (4) process and that process is required to be remediated, before the final cleaning process can be validated. However, your Engineering Manager stated the remediation to your firm's (b) (4) process is still in investigational phase and does not currently have a defined action plan under CAPA CA-3092. The debris from your (b) (4) process was first identified as the cause of particulates on your product in October 2016, as part of the retrospective testing completed under CAPA CA-02936, in Attachment 14.

C. CAPA 02719 (assigned a risk score of (b) (4)), opened in July, 2016, identifies the need to remediate Design History Files (DHF's) as design control issues such as ambiguous design inputs, verification not demonstrating design outputs met design inputs, design transfer and inadequate statistical l techniques for V & V activities which were identified though third party audits and FDA inspections and to obsolete DHFs for other devices. As part of this CAPA, you performed a DPR (device performance review) for all DHFs to determine if any actions need to be taken (such as recall) for devices which have been and are currently being distributed.

These "DPR" evaluations were conducted using 1) review of national registries; 2) literature reviews and 3) occurrence rates of revision surgeries associated with serious adverse events. Since your DPR evaluation only uses one subset of complaints/MDRs (revision surgery) you have not demonstrated that you have taken a plenary "risk based" approach to evaluating products that have been and are still being distributed. Other high risk failure modes (which could result in an MDR) such as; pain, implant not assembling with mating implant, limited range of motion or fracture, have not been included in your DPR evaluations.

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A data sort using the previous 6 months of MDR data (October 1, 2017-April 17, 2018) for implants associated with "functional performance", found the highest occurrence rates were from the "Comprehensive Reverse" product line, which is part of the extremities segment of devices. A review of the DHF (comprehensive shoulder implant) for the XL-115363, which appears to be "high" risk based on MDR events, has not yet been fully remediated, found the following;

i. Your input-output risk table has not been updated with potential severity levels associated with hazards. For instance hazard line (b) (4) for inadequate packaging leading to infection is assigned a severity score of (b) (4) equating to "Necessitates minor medical intervention" in your Risk Management Procedure QM 4.4, Rev 13. This assigned severity level does not include the potential severity outcomes of serious injury or death which can occur as a result of infection.

ii. On 4/20/2018, your Director of Engineering Services stated that your occurrence scores on your input-output risk table are not currently reflective of similar family types, which is planned as part of your remediation effort. Therefore, it is unknown if residual risk levels are currently acceptable.

iii. Not all feedback from design validation was considered prior to releasing the product. One of the surgeons used for design validation wanted to make sure the (b) (4) works with (b) (4)). This was not addressed during the design project.

iv. You have no documented statistical rational for verification or validation activities. For example, you used only (b) (4) surgeons for design validation and (b) (4) samples for testing design inputs 4.1 and 4.3 regarding torsion and shear testing.

v. Design verification did not document all test conditions for design inputs 4.1 and 4.3. Load rates (lbs/sec), defined in the protocols were not documented in any of the (b) (4) test reports.

vi. Design verification testing did not demonstrate your design input was met for design input 4.3. Your specification for maximum allowable motion for the glenosphere baseplate of (b) (4) inches after load showed a result of (b) (4) inches which was accepted as the "mean" testing for the part was (b) (4) inches (still out of specification). Additionally, part (b) (4) was missing test results.

vii. *Design inputs in your input-output risk table are ambiguous. For example, input 2.2; Range of Motion results meeting surgeon expectations. A comparison of your design inputs records which have been "remediated" show (b) (4) inputs have been updated from your input-output risk table. It is currently unknown if the current level of verification or validation for these inputs will require new or additional testing.

viii. *Not all design inputs have been established. Your design input records which have been remediated show (b) (4) design inputs which are missing from your input-output risk table. It is currently unknown if these design inputs have undergone verification or validation activities or if this testing may be covered under a different design project.

*The "remediated" design inputs for this device became effective 4/9/18 during this inspection include new inputs and address inputs which were ambiguous. The remaining design stages (for example; verification testing, validation and risk management) have not yet been remediated in this DHF.

D. *WI070002: NCR Quality Trending* (Rev. 1) instructs to (b) (4) However, on 4/17/2018, your firm's Interim VP of QA/RC and Engineer Manager confirmed that common cause rework (CCR) data has never been reviewed as a quality data source. CCRs are intended to document corrections and rework for "cosmetic" nonconformities.

E. Only one defect code is assigned to NCRs having multiple deficiencies documented in a single record. On 4/18/2018, your Engineer Manager for Central Engineering stated that only the defect code is trended per *WI070002: NCR Quality Trending* (Rev. 1). For example, the following NCRs contain

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information regarding nonconformances that were not trended:

NCR #	Description/Findings	Defect Code
NCR12197758	"tape gum, missing porous and discoloration"	SU01-Surface Defect
NCR12185478	"2 parts have scratches on them. All 8 parts have fuzz particles."	MA03-Foreign Material
NCR12220917	"1. Found fuzz all inside porous, 2. Found pits and scratches on the critical Surfaces"	MA03-Foreign Material
NCR12177720	"1) Tape gum between porous and 30 grit surfaces. 2) Parts have been assembled and there is no approved rework"	MA03-Foreign Material

OBSERVATION 2

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

This is a repeat observation from the FDA inspection dated 9/12/2016 to 11/22/2016.

Specifically,

During the previous FDA inspection, the validation of (b) (4)) sterilization Cycle (b) (4) was found to not provide objective evidence that devices are sterilized with an (b) (4) as purported by the validation report. The cycle was used to sterilize (b) (4) and Sports Medicine devices.

Since then, your firm has validated a new (b) (4) sterilization cycle (Cycle (b) (4)) which utilizes a new (b) (4) and (b) (4) totes "(b) (4) ." However, Cycle (b) (4) was not revalidated and the studies

performed in lieu of revalidation did not provide objective evidence that devices currently in distribution meet an (b) (4) For example:

A. Products sterilized by Cycle (b) (4) underwent technical review by (b) (4) sterilization SMEs to (b) (4) " (b) (4) Sports Medicine products failed to meet acceptance criteria and were subjected to (b) (4) cycle study. The study demonstrated that three (3) of the (b) (4) (b) (4) products were more difficult to sterilize than the (b) (4) historically used for Cycle (b) (4) Juggerknot 2.9MM w/ Needles (item #110005096), Juggerknot Mini (item #912076), and Juggerloc B2B (item #110007345/110007337).

B. The three (3) products were then subjected to a (b) (4) minute) study. The study protocol (#201606011, Rev. 02, approved 1/13/2017) states "(b) (4) ". The actual location used was not documented; however, on 4/13/2018, your Principal Sterilization Associate said he and his team placed the devices in the (b) (4) of the (b) (4) This (b) (4) study and Cycle (b) (4) utilized (b) (4) which only feature (b) (4) around the (b) (4) and (b) (4) of the (b) (4) lid. Justification for choosing the (b) (4) of the (b) (4) instead of the (b) (4) was not documented.

C. A BI placed in (b) (4) location of one of the Juggerknot Mini device subjected to the (b) (4) study (item (b) (4)) failed sterility testing. Subsequently, your firm subjected the failed product to a (b) (4) ((b) (4) minute) study, in which all BIs tested negative for growth. Again, the actual location in which the products were placed was not documented, but your Principal Sterilization Associate said he and his team used the (b) (4) of the (b) (4) Justification for this location was again not documented.

D. The (b) (4) and (b) (4) studies do not demonstrate repeatability of the Cycle (b) (4) sterilization process. *SOP 9.4.4:* (b) (4) *Process Validation Method* (Rev. 5, effective 9/14/2011) states "(b) (4) ." Your firm's (b) (4) sterilization SME confirmed this was not done during the study because "this was

not a validation."

OBSERVATION 3

Risk analysis is inadequate.

Specifically,

Per your Design Controls Procedure, QM 4.3, Rev 10, risk management activities shall occur pursuant to Risk Management Procedures QM 4.4, and shall be incorporated in the design history file as defined in SOP 4.4.1 Design Risk Management and SOP 4.4.2 Process Risk Management.
You establish a risk priority number (RPN) for your PFMECA's as a mathematical product of the (b) (4) (b) (4), with RPN scores of (b) (4) or more requiring further mitigation.
A review of PFMECA PF0700, Rev 4, regarding Sterile Packaging found the following:

A. Inconsistences in the assignment of severity scores for failure modes with the same "Potential Failure" effects. For example, the failure effect of "Compromise of the product Sterility" is given severity of scores of (b) (4) (necessitates minor medical intervention) **or** (b) (4) (results in permanent impairment of body function or damage to body structure/ necessitates surgical intervention) for different potential failure modes. This failure effect regarding sterility was assigned a level of (b) (4) for (b) (4) line items and a level of (b) (4) in (b) (4) line items in this PFMECA. Using a severity level of (b) (4) for the failure effect of product sterility for all failure modes would result in (b) (4) of the hazard lines exceeding the acceptable level of (b) (4) and requiring further mitigation.

B. Your assignment scores of the potential severity rating in your PFMEA for the possible outcomes related to sterility issues, such as infection, are not commensurate with your current Master Harms Index, CF03000, Rev 2., which links harm descriptions to the severity of the harm. For example, the harm of infection has a potential severity as high as (b) (4) (b) (4) "Catastrophic") in your Master Harms Index for a severe systemic infection including sepsis. Your PFMEA assigns scores of (b) (4) or (b) (4) as potential severity levels associated with the failure effect of compromising of product sterility.

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OBSERVATION 4

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

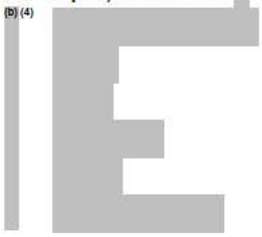
This is a repeat observation from the FDA inspection dated 9/12/2016 to 11/22/2016.

Specifically,

Your firm did not ensure adequate test methods are used by your contract lab, Supplier A. Per SOP 28.0.1, "Process Monitoring of Final Cleaning," Revision 9, testing for all products without an approved cleaning validation is required to undergo (b) (4) and (b) (4) testing. This testing is contracted to supplier A, but there was no completion of an assessment of the test method validation used by supplier A or your firm for adequacy of use with your firm's products.

For example, there are (b) (unique types of polymer materials used at your firm's location:

(b) (4)



None of these (b) (4 polymers have a documented justification on why the current test methods are acceptable for the unique materials. Additionally, there is no documented justification that all of your firm's products do not present a new worst case scenario for the current test method.

OBSERVATION 5

Procedures to control environmental conditions have not been adequately established.

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This is a repeat observation from the FDA inspection dated 9/12/2016 to 11/22/2016.

Specifically,

A. Environmental excursions have not been adequately investigated. All versions of IC 001: Increased Environmental Monitoring of Work Environments, and cleanrooms and *SOP 9.5.15: Environmental Monitoring of Environmentally Controlled Areas* effective since 3/17/2017 require confirmed environmental action-limit excursions to be investigated via an NCR. Since 3/24/2017, at least (b) (4) NCRs have been initiated for microbial environmental action-limit excursions. At least 23 of these (b) (4) excursions have not been adequately investigated. Specifically, the investigations documented in the 24 NCRs were limited to re-sanitization and retesting. Investigations into the cause of the excursions were not documented.

B. We observed employee practices that violate *SOP 9.5.17: Environmentally Controlled Areas: Cleanroom and Work Environment Practices* (Rev. 4, effective 2/1/2018), which instructs "(b) (4) " For example:

   i. Employees load devices onto racks in an uncontrolled environment and place them onto (b) (4) , which transport the loaded racks to environmentally controlled hoods. On 4/9/2018, we observed racks present in (b) (4) and (b) (4) Attached above the racks were "mailboxes" used to hold work order documentation. Interviews with employees revealed that racks are sent back to the uncontrolled environment via a pass-through. The racks are then reused without sanitizing the mailboxes.

   ii. In the (b) (4) Work Environment on 4/9/2018, we observed an employee remove a sheet of "flower paper" from its open package on his work station and take it into an environmentally controlled hood.

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OBSERVATION 6

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

This is a repeat observation from the FDA inspection dated 9/12/2016 to 11/22/2016.

Specifically,

Your firm's procedures QM 13.1, "Control of Nonconforming Product," revs 4-8 and SOP 13.1.1, "Nonconforming Product Procedure," revs 3-7, do not ensure that nonconforming products are documented in a consistent manner. For example,

A. Your procedures do not ensure that your operators and engineers consistently open a NCR or CCR as required. For example,

   i. SOP 13.1.1 does not clearly define when NCR or "common cause rework" (CCR) records should be initiated for nonconforming product. The procedure defines CCR as "(b) (4) ." Per the procedure, NCRs are required to be formally investigated whereas CCRs are not.

   On 4/16/2018, your Senior Quality Engineer II stated that the "common causes of NCRs" listed in Section 7.9 of the procedure in fact are cases where CCRs should be initiated. We observed inconsistency in whether NCRs or CCRs are initiated for apparently the same reasons. For example, CCR12224142 and NCR12224112 were initiated on 3/20/2018 due to "3pcs has tape gum on glass bead blast" and "tape gum staining and residue", respectively. Both nonconformances were found in the same work center (b) (4)). Between 9/13/2017 and 4/9/2018, your firm has initiated a total of (b) (4) NCRs and (b) (4) CCRs that contain the words "tape gum" in any of the "free cells."

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B. Your firm inconsistently assigns defect codes based on the nonconformances documented in the NCR/CCR. For example,

i. NCR12199179 was initiated due to "Tape gum on porous" on or around 12/18/2017. The NCR was assigned a defect code of "MA03-Foreign Material."

ii. NCR12185478 was initiated due to "tape gum on the porous" on or around 10/18/2017. The NCR was assigned a defect code of "MA02-Defective Material."

iii. CCR12217977 was initiated due to "Hair found in packaging," on or around 2/27/2018. The CCR was assigned a defect code of "MA02-Defective Material."

iv. CCR12193114 was initiated due to "Hairs found inside blister packaging" on or around 11/24/2017. The CCR was assigned a defect code of "MA03-Foreign Material."

OBSERVATION 7

Procedures for acceptance activities have not been adequately established.

This is a repeat observation from the FDA inspection dated 9/12/2016 to 11/22/2016.

Specifically,

You do not have a documented rationale to support acceptance criteria defined in your in-process packaging seal inspection procedure I00051.3, version 2, which allows up to (b) (4) particles (b) (4) in sterile package seals or why "red" or particles (b) (4) are un-acceptable.

OBSERVATION 8

Procedures for training and identifying training needs have not been established.

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Specifically,

Your firm's training procedures SOP 18.0.1, rev 12, "Training Identification and Documentation," effective 27-Mar-18 and QM 18.0, rev. 8, "Training," effective 27-Mar-2018, do not ensure that all employees are adequately trained. For example,

A. Your firm's operators were unable to identify procedures related to their operations and did not perform operations per your firm's work instructions. During a walkthrough in the (b) (4) manual cleaning area on 04/09/2018, an employee was unable to identify what the process specification referenced for a step of manual cleaning referenced in section 11, step (b) (4) of WCLN017, "(b) (4) Revision 1. Another employee in your (b) (4) cleaning area on 04/09/2018 was unable to locate the procedure used for cleaning your (b) (4) after manually cleaning the product. Additionally, this employee stated they were on ste (b) (4) f section 11 in WCLN017, but had already (b) (4) from the product, which is meant to remain on the product until step (b) (4) Additionally, they were not using a wire brush to remove debris, as stated in step (b) (4) but a nylon brush, as is described in step (b) (4) There was no wire brush observed at their station. They stated they use a nylon brush, instead of a wire brush, as the wire brush can scratch the polished surfaces. The polished surface was previously covered (b) (4)

B. During a second walkthrough of the facility on 04/17/2018, an operator was observed measuring part (b) (4) for specification (b) (4) as part of their line clearance activities. According to specification 193114-DWG-1 Rev. B, specification (b) (4) upper limit should measure (b) (4) with a tolerance of (b) (4). Your operator measured this specification (b) (4) for the first part as (b) (4) and the second part as (b) (4) and stated the part was "good." These measurements were not identified as non-conformances until the operator was directly asked what the specification was and if the parts were conforming.

C. On 4/9/2018, your firm's employee in packaging, used a (b) (4) gauge to measure the tray seal in the (b) (4) packaging area. Your firm's "Package Requirements" states that the narrowest seal width for "Seal Width-Trays" is "not less than (b) (4)." Your employee stated that the only gauge at her station

was the (b) (4) gauge.

D. During an inspection of the sterile sealing process with asset number (b) (4) on 4/9/2018, the sealer operator did not properly demonstrate how to measure seal width using a gauge per procedure 100051.3, version 2. The operator incorrectly measured an area outside of the blister package seal.

E. On 4/9/2018, an operator manufacturing part number (b) (4)) using automated diameter system referred to the (b) (4) limits for the product specifications (b) (4)) and not the correct tolerances of (b) (4) mm. Therefore, there is a subset of measurements which could be non-conforming and not captured or entered into the firm's non-conforming database.

OBSERVATION 9

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

This is a repeat observation from the FDA inspection dated 9/12/2016 to 11/22/2016.

Specifically,

SOP 28.0.3: Sterile Packaging Sealer Monitoring (Rev. 5, effective 1/26/2018) requires periodic monitoring of packaging seal strength and integrity. It states (b) (4)

Though not clearly stated in the procedure, your firm's Vice President of Quality Assurance stated it was intended to require seal strength and integrity testing to be performed on samples from both the (b) (4) and (b) (4)

(b) (4) . However, you were unable to provide objective evidence that this process is followed because traceability between test samples and (b) (4) is not documented.

Furthermore, on 4/11/2018, your firm's Quality Technician stated he performs seal integrity testing only on samples from the (b) (4) of the run and seal strength testing only on samples taken at the (b) (4) of the run.

Notably, your firm relies on such process monitoring as justification for continuing to package devices using sealers whose process validations are known to be inadequate.

OBSERVATION 10

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established.

This is a repeat observation from the FDA inspection dated 9/12/2016 to 11/22/2016.

Specifically,

Process controls for packaging sealer Asset (b) (4) have not been adequately established.

The *Heat Sealing Parameter Sheet (HSPS)* for Asset (b) (4) (Rev. 4, effective 3/22/2018) specifies the pressure setting as "NA". The respective process validation (Validation Report #487) stated that pressure is "not considered critical" because it is "fixed on the machine and cannot be changed." However, the Operating Instructions manual for the sealer explains:

E. Contact pressure may be adjusted by positioning the (b) (4) and adjusting it using an (b) (4) .
F. Pressure may be read-out using the sealer (b) (4) function.
G. The (b) (4) function "should be performed before the (b) (4) working process and should be documented by filing the print out."
H. Too low of pressure could result in a seal that "does not hold", which may be remedied by readjusting

the pressure of the (b) (4).

The (b) (4) function is not mentioned in *WEQP168: Work Instructions, Packaging – Auto – Sterile Sealing Machines* (Rev. 4, effective 4/9/2018) or *QM 9.7: Manufacturing Equipment Maintenance* (Rev. 22, effective 11/28/2017). Interviews with an operator on 4/10/2018 and maintenance personnel on 4/11/2018 revealed the (b) (4) function is not used.

Asset (b) (4) is one of (b) (4) sealers used since the previous FDA inspection. The othe (b) (4) were removed from service on (b) (4)

OBSERVATION 11

Procedures to ensure equipment is routinely calibrated, inspected, checked and maintained have not been adequately established.

Specifically,

The preventive maintenance plan for packaging sealer Asset (b) (4) requires to "ENSURE THAT DISTANCE BETWEEN SEALING DIES IS (b) (4) MM" on (b) (4) basis. On 4/11/2018, your firm's Maintenance Technician stated he used a (b) (4) gage to verify the distance of (b) (4) mm during the most recent (b) (4) maintenance on 5/8/2017. The (b) (4) gage is not tracked or calibrated by your firm's metrology department. He said he had used the gage since being hired in 1997. On 4/11/2018, we observed the gage to appear visibly corroded and damaged.

QM 11.0: Control of Inspection, Measuring, and Test Equipment (Rev. 8) requires that "Measurement and test equipment shall be identified with a unique identification number and the calibration due date" and "The quality department shall maintain an electronic real-time calibration schedule by gage number".

The Operating Instructions manual for packaging sealer Asset (b) (4) states that too great a distance between sealing dies could result in a seal that "does not hold".

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	FEI NUMBER 1825034

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

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

FIRM NAME	STREET ADDRESS
Zimmer Biomet, Inc.	56 E Bell Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Warsaw, IN 46582	Medical Device

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
Observation 9: Not annotated
Observation 10: Not annotated
Observation 11: Not annotated

*DATES OF INSPECTION

4/09/2018(Mon), 4/10/2018(Tue), 4/11/2018(Wed), 4/12/2018(Thu), 4/13/2018(Fri), 4/16/2018(Mon), 4/17/2018(Tue), 4/18/2018(Wed), 4/19/2018(Thu), 4/20/2018(Fri), 4/23/2018(Mon), 4/24/2018(Tue)

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