

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 07/06/2011 - 07/22/2011*
	FBI NUMBER 1000220733

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Jeffery A. McCaulley, President, Zimmer Reconstructive**

FIRM NAME Zimmer Inc.	STREET ADDRESS 345 E. Main Street
CITY, STATE, ZIP CODE, COUNTRY Warsaw, IN 46580-2304	TYPE ESTABLISHMENT INSPECTED 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:**

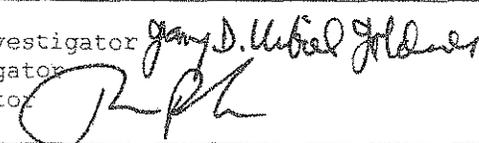
**CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)**

**OBSERVATION 1**

Procedures for corrective and preventive action have not been established.

Specifically, your firm has not fully implemented "Corrective and Preventive Action System," Doc. # SOP (b) (4), Revs. 0, 1, and 2, dated 04/28/1999, 10/28/2002, and 01/12/2004, respectively, "Corrective and Preventive Action Process," Doc. # SOP (b) (4), Revs. 3 through 9, dated 04/12/2006 through 04/08/2011, respectively, and "Zimmer Global Corrective and Preventive Action Procedure," Doc. # ZOP (b) (4), Rev. 0, dated 11/02/2009. In Doc. # ZOP (b) (4), Rev. 0, and SOP (b) (4), Revs. 0 through 9, your firm documents requirements to identify corrective and preventive actions. SOP (b) (4), Rev. 9, requires the identification of (b) (4). "Corrective action is defined by your firm in Doc. # ZOP (b) (4), Rev. 0, and SOP (b) (4), Revs. 6 through 8, to include (b) (4). In SOP (b) (4), Revs. 3 through 5, your firm defines corrective action as (b) (4). (b) (4) Corrective action is defined by your firm in SOP (b) (4), Revs. 1 and 2, as (b) (4). (b) (4) However, your firm did not identify all of the actions necessary to correct and prevent the recurrence of nonconformities of ZMR Hip System implantable femoral prostheses.

Although your firm documents in the most recent twelve (12) of (b) (4) total ZMR Hip System Instructions For Use that these implantable femoral prostheses are contraindicated for patients with poor bone stock, 510(k) notifications for the ZMR Revision Taper Hip Prosthesis (K992667, dated 10/27/1999) and the ZMR Porous Revision Hip Prosthesis (K994286, dated 03/10/2000) document that these devices are "intended for cementless revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur." Your firm's management confirmed that: individuals who have experienced a

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fracture of these devices nearly always undergo a minimum of three (3) hip arthroplasty surgical operations; and fracture of these devices following implantation always requires a revision surgery to implant a new femoral prosthesis into the affected patient.

The 510(k) notifications, K992667 and K994286, document that these implantable femoral devices consist of three (3) components- a proximal segment or "body," a distal stem, and a compression nut- that are intraoperatively assembled to construct the device. According to your firm's current ZMR Hip System marketing literature, the modularity of ZMR Revision Taper and ZMR Porous Revision prostheses enables all three (3) proximal body options- Cone Body, Calcar Body, and Spout Body- to be used with any of the distal stem choices- Taper Stem, Porous and Porous Slotted Stems, and Spline Stem. Prior to 12/13/2002, your firm manufactured, distributed, and sold an additional fourth proximal body style for the ZMR Hip System, the taper proximal body.

On 12/13/2002, your firm wrote to the German authorities at the Federal Institute for Drugs and Medical Devices following your firm's receipt of twenty (20) reports of ZMR Hip System prosthesis failures. Your firm documents in this letter that "analysis of these failures indicates the predominant failure mode is inadequate proximal bone support of the prosthesis leading to fatigue failure of the stem at the proximal end." Notably, your firm documents in this letter concern "that continued failure to follow the warnings, contraindications, and surgical technique provided for the product may lead to additional failures. Accordingly, Zimmer is halting the distribution and sale of those portions of the ZMR system that have been most frequently involved with the failures, the proximal taper body family of products. This action should be completed, on a worldwide basis, by the end of this month." However, your firm did not identify all of the actions necessary to correct and prevent the recurrence of fractures in ZMR Revision Taper and ZMR Porous Revision femoral prostheses.

According to "Plan for (b) (4) dated 07/14/2008, your firm documents that following the market withdrawal of the ZMR Taper Proximal Body in December 2002, your firm received numerous complaints reporting fracture of ZMR Revision Taper and ZMR Porous Revision femoral prostheses, in all combinations of proximal body and distal stem. For example, out of one hundred thirty-four (134) complaints received by your firm between 03/01/2003 and 01/27/2009 regarding ZMR Revision Taper and ZMR Porous Revision femoral prosthetic devices, your firm received one hundred one (101) complaints, approximately 73%, alleging fractures in these devices following implantation into patients. Your firm subsequently confirmed that these one hundred one (101) complaints are one hundred one (101) instances of ZMR Revision Taper and ZMR Porous Revision femoral prostheses that fractured following implantation, and which therefore required a revision surgery to implant a new femoral prosthetic device into the affected patient. Examples of these one hundred one (101) instances include:

- (A) Complaint # REC-000734, dated 03/27/2007, which reports, "Fractured hip stem. Patient died shortly after revision." This complaint includes a letter to your firm from an orthopedic surgeon who wrote, "As discussed on the phone I enclose the Zimmer implant with a fractured stem. This was initially implanted with excellent proximal support but subsequent osteolysis from around the body section resulted in loosening at the site. (b)(4); (b)(6) (b)(4); (b)(6) (b)(4); (b)(6) and I wonder if you can clarify if Zimmer has taken on liability for the fracture of this component." Your firm documents in this complaint that the ZMR Hip System components involved in this device fracture include a ZMR Taper Distal Stem (20mm x 185mm)

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and a ZMR Spout A Proximal Body (46mm x 45mm, Extended Offset).

- (B) Complaint # RBASE-C612147, dated 12/19/2006, which reports that "approx. 4.5 yr. post-op stem broke at cone body junction/revision required."
- (C) Complaint # RBASE-040061, dated 06/30/2004, which reports that "approx. 4 yr. post-op porous stem broke at calcar body junction/revision required."
- (D) Complaint # RBASE-356575, dated 09/29/2003, which reports that "approx. 20 mo. post-op taper stem broke at taper body junction/revision required."

On 06/23/2008, your firm initiated CAPA # WHIP-062308-001 to address fractures in ZMR Revision Taper and ZMR Porous Revision femoral prostheses following implantation. Notably, your firm closed CAPA # WHIP-062308-001 on 01/27/2009, documenting, "No corrective actions are planned at this time based on the residual risk benefit decision. Therefore no verification plan is warranted." However, your firm did not identify all of the actions necessary to correct and prevent the recurrence of fractures in ZMR Revision Taper and ZMR Porous Revision femoral prostheses. For example, out of fifty-seven (57) complaints received by your firm between 02/01/2009 and 07/14/2011 regarding these devices, your firm received thirty-eight (38) complaints, approximately 67%, alleging fractures in ZMR Revision Taper and ZMR Porous Revision femoral prostheses following implantation into patients. Your firm subsequently confirmed that these thirty-eight (38) complaints are thirty-eight (38) instances of ZMR Revision Taper and ZMR Porous Revision femoral prostheses that fractured following implantation, and which therefore required a revision surgery to implant a new femoral prosthetic device into the affected patient. Examples of these thirty-eight (38) instances include:

- (D) Complaint # CPT110003648, dated 04/29/2011, which reports that "the ZMR stem fractured just below the proximal body," and that "the product was in vivo approximately 18 months at the time of revision." Your firm documents in this complaint that the ZMR Hip System components involved in this device fracture include a ZMR Porous Distal Stem (18mm x 170mm, Straight) and a ZMR Cone D Proximal Body (46mm x 35mm, Extended Offset).
- (E) Complaint # CPT100005730, dated 10/28/2010, which states, "It is reported by patient's counsel that patient underwent total hip arthroplasty on (b) (6). Postoperatively on an unknown date, the stem fractured and patient was revised on (b) (6)." Your firm documents in this complaint that these "implants were in-vivo approximately 5 years 9 months," and that the ZMR Hip System components involved in this device fracture include a ZMR Porous Distal Stem (16.5mm x 170mm, Bowed) and a ZMR Cone C Proximal Body (40mm x 35mm, Standard Offset).
- (F) Complaint # REC-010766, dated 07/13/2009, which reports, "It is reported by patient's counsel that patient underwent total left hip revision on or about (b) (6). At about 14 months post-op, on (b) (6) patient was moving from a treatment table to an X-ray table when (b) (6) felt a sudden and sharp increase of pain in (b) (6) hip. X-rays taken immediately thereafter revealed a fracture of the proximal stem of the femoral prosthesis." Your firm documents in this complaint that the ZMR Hip System components involved in this device fracture include a ZMR Taper Distal Stem (18mm x 135mm) and a ZMR Cone B Proximal Body (40mm x 35mm, Standard Offset).

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According to your firm's management on 07/21/2011, the totality of actions identified and taken by your firm to correct and prevent the recurrence of fractures in ZMR Revision Taper and ZMR Porous Revision femoral prostheses following implantation into patients is:

- Market withdrawal on 12/13/2002 of ZMR Taper Proximal Body;
- CAPA # WHIP-062308-001, initiated on 06/23/2008 and closed 01/27/2009, with no corrective actions planned and no verification plan warranted; and
- CAPA # CP00000090, initiated on 07/20/2011 "to determine the continued safety and efficacy" of the ZMR system.

**DESIGN CONTROLS**

**OBSERVATION 2**

Design validation did not ensure the device conforms to defined user needs and intended uses.

Specifically, your firm has not fully implemented "Design Verification, Design Validation," Procedure # (b) (4) Revs. 1, 2, and 3, dated 01/02/1998, 02/01/1999, and 04/07/2000, respectively. Your firm documents that this procedure defines and controls the processes and documentation of design verification, design validation, and reconciliation of design outputs to inputs. In this procedure, your firm defines that (b) (4) (b) (4) (b) (4) However, your firm has not ensured that design validation for ZMR Hip System implantable femoral prostheses conforms to defined user needs and intended uses.

The 510(k) notifications for the ZMR Revision Taper Hip Prosthesis (K992667, dated 10/27/1999) and the ZMR Porous Revision Hip Prosthesis (K994286, dated 03/10/2000) document that these implantable femoral devices consist of three (3) components- a proximal segment or "body," a distal stem, and a compression nut- that are intraoperatively assembled to construct the device. According to your firm's current ZMR Hip System marketing literature, the modularity of ZMR Revision Taper prostheses and ZMR Porous Revision prostheses enables all three (3) proximal body options- Cone Body, Calcar Body, and Spout Body- to be used with any of the distal stem choices- Taper Stem, Porous and Porous Slotted Stems, and Spline Stem. Although your firm documents in the most recent twelve (12) of (b) (4) total ZMR Hip System Instructions For Use that these implantable femoral prostheses are contraindicated for patients with poor bone stock, 510(k) notifications, K992667 and K994286, document that they are "intended for cementless revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur."

Your firm identifies additional user needs and intended uses for ZMR Hip System implantable femoral prosthetic devices in the product labeling warnings on pages 27 and 28 of the most recent "ZMR Porous Revision Hip Prosthesis Surgical Technique." These warnings state, "Stem fracture, particularly in heavy, physically active patients, is most likely to occur in a prosthesis that is not supported proximally." Notably, your firm's management agreed that "heavy," "physically active,"

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and "supported proximally" are subjective terms used by your firm. However, for ZMR Revision Taper and ZMR Porous Revision femoral prostheses, your firm has not performed design validation for all body-stem combinations and/or the worst case scenario body-stem combination, to establish, through objective measurable data: the patient weight(s) that will result in stem fracture; the patient activity level(s) that will result in stem fracture; the amount and quality of proximal support in the patient that will result in stem fracture; and the combination of patient weight(s), patient activity level(s), and amount and quality of proximal support in the patient that will result in stem fracture.

Out of two hundred seventeen (217) complaints received by your firm between 05/07/2001 and 07/14/2011 regarding ZMR Revision Taper and ZMR Porous Revision femoral prosthetic devices, your firm received one hundred fifty-nine (159) complaints, approximately 73%, alleging fractures in these devices following implantation into patients. Your firm subsequently confirmed that these one hundred fifty-nine (159) complaints are one hundred fifty-nine (159) instances of ZMR Revision Taper and ZMR Porous Revision femoral prosthetic devices that fractured following implantation, and which therefore required a revision surgery to implant a new femoral prosthesis into the affected patient. Examples of these one hundred fifty-nine (159) instances include:

- (A) Complaint # REC-011681, dated 09/28/2009, which reports, "During 3 weeks increasing pain in (b)(6) high. At (b)(6) (b)(6) felt a breaking sensation in the thigh and was unable to stand/walk and was admitted to hospital." Your firm documents that this "patient is a (b)(6) (b)(6) X-rays were returned for evaluation. X-rays at time of event (b)(6) clearly show stem fracture. Surgeons notes indicate rheumatoid arthritis with poor bone stock. No devices were returned and they were in situ for 6 years and 8 months." Your firm documents in this complaint that the ZMR Hip System components involved in this device fracture include a ZMR Taper Distal Stem (18mm x 185mm) and a ZMR Taper Proximal Body.
- (B) Complaint # REC-000734, dated 03/27/2007, which reports, "Fractured hip stem. Patient died shortly after revision." This complaint includes a letter to your firm from an orthopedic surgeon who wrote, "As discussed on the phone I enclose the Zimmer implant with a fractured stem. This was initially implanted with excellent proximal support but subsequent osteolysis from around the body section resulted in loosening at the site. (b)(4); (b)(6) (b)(4); (b)(6) and I wonder if you can clarify if Zimmer has taken on liability for the fracture of this component." Your firm documents in this complaint that the ZMR Hip System components involved in this device fracture include a ZMR Taper Distal Stem (20mm x 185mm) and a ZMR Spout A Proximal Body (46mm x 45mm, Extended Offset).
- (C) Complaint # RBASE-040140, dated 11/11/2004, which reports that "approx. 43 days post-op stem broke at body junction/revision required."

**OBSERVATION 3**

Procedures for design output have not been established.

Specifically, your firm has not fully implemented "Design and Design Specifications," Procedure # (b)(4) Revs. 1 and 2,

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dated 01/02/1998 and 02/01/1999, respectively, and "Design Specifications (Outputs)," Procedure # (b) (4) Rev. 3, dated 04/07/2000. Your firm documents that Procedure # (b) (4) defines and controls the processes and document flow for design and design specifications for new products. Your firm defines design specifications in this procedure as (b) (4) (b) (4). However, your firm has not ensured that design specifications (outputs) essential for the proper functioning of ZMR Hip System implantable femoral prostheses are identified.

The 510(k) notifications for the ZMR Revision Taper Hip Prosthesis (K992667, dated 10/27/1999) and the ZMR Porous Revision Hip Prosthesis (K994286, dated 03/10/2000) document that these implantable femoral devices consist of three (3) components- a proximal segment or "body," a distal stem, and a compression nut- that are intraoperatively assembled to construct the device. According to your firm's current ZMR Hip System marketing literature, the modularity of ZMR Revision Taper prostheses and ZMR Porous Revision prostheses enables all three (3) proximal body options- Cone Body, Calcar Body, and Spout Body- to be used with any of the distal stem choices- Taper Stem, Porous and Porous Slotted Stems, and Spline Stem. Although your firm documents in the most recent twelve (12) of (b) (4) total ZMR Hip System Instructions For Use that these implantable femoral prostheses are contraindicated for patients with poor bone stock, 510(k) notifications, K992667 and K994286, document that they are "intended for cementless revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur."

Your firm identifies additional user needs and intended uses for ZMR Hip System implantable femoral prosthetic devices in the product labeling warnings on pages 27 and 28 of the most recent "ZMR Porous Revision Hip Prosthesis Surgical Technique." These warnings state, "Stem fracture, particularly in heavy, physically active patients, is most likely to occur in a prosthesis that is not supported proximally." Notably, your firm's management agreed that "heavy," "physically active," and "supported proximally" are subjective terms used by your firm. However, for ZMR Revision Taper and ZMR Porous Revision femoral prostheses, your firm has not defined or documented design specifications (outputs) that, for all body-stem combinations and/or the worst case scenario body-stem combination, relate the following variables, through objective measurable data, to minimizing stem fracture: patient weight; patient activity level; amount and quality of proximal support in the patient; and a combination of patient weight, patient activity level, and amount and quality of proximal support in the patient.

**OBSERVATION 4**

Procedures for design input have not been established.

Specifically, your firm has not fully implemented "Design Inputs and Approvals," Procedure # (b) (4) Revs. 1, 2, and 3, dated 01/02/1998, 02/01/1999, and 04/07/2000, respectively. Your firm documents that this procedure "defines and controls the process for establishing and reviewing the design inputs for new products." Your firm defines design inputs in Procedure # (b) (4) Revs. 1, 2, and 3, as (b) (4) (b) (4). However, your firm has not ensured that design requirements for ZMR Hip System implantable femoral prostheses address the intended use of these devices, including the needs of the patient.

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**PRODUCTION AND PROCESS CONTROLS (P&PC)**

**OBSERVATION 5**

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

Specifically,

**PART A: TITANIUM ALLOY/TRABECULAR METAL HIP CUP DIFFUSION BONDING**

Your firm's Global Standard Operating Procedure (GSOP) (b) (4) titled *Validation/Qualification Protocol Development Overview* (Revision 0, effective 11/22/2005), was not fully implemented at its time of use. The Purpose of the procedure is (b) (4) (b) (4)

Your firm operates a process known as *diffusion bonding* to bond together two dissimilar metal materials (*Trabecular Metal* and *Titanium*) by placing the (b) (4)

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(b) (4)

Trabecular Metal (TM) is a Zimmer-patented porous tantalum material, and Tivanium is Zimmer's trademark name for titanium alloy Ti-6Al-4V.

Products processed by diffusion bonding in your firm's (b) (4) TM manufacturing cell include:

- TM Modular Cup
- Continuum Cup (also known as the (b) (4))
- Trilogy Fiber Metal IT (where "IT" denotes "integrated taper")

Products processed by diffusion bonding in your firm's TM Diffusion Bonding and Fiber Metal Hip Stem manufacturing cells include:

- NexGen TM Tibia Plate
- NexGen Fiber Metal Tibia Plate
- TM Humeral Stem
- TM Reverse Stem
- TM Reverse Baseplates
- TM Primary Hip Stem
- Epoch Fiber Metal Hip Stems (sizes 11, 12, and 13)
- VerSys Fiber Metal Hip Stems
- Mayo Hip

The Continuum Cup is the hip cup component of your firm's Continuum Acetabular System. Your firm's indications for use state that:

- The system is indicated for primary or revision surgery in skeletally mature individuals for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses
- The system is intended for use either with or without bone cement in total hip arthroplasty

The Continuum hip cup is made up primarily of two components, which are married via the diffusion bonding process:

- A Trabecular Metal "shell" (porous tantalum that is proximal to the patient's acetabulum when implanted)
- A Tivanium "substrate" (titanium alloy that is distal to the patient's acetabulum when implanted)

Your firm's Final Validation/Qualification Report for Titanium/Trabecular Metal Cup Diffusion Bonding (Project # (b) (4) Revision 0) was approved on 1/19/2009. The report states that "The Trabecular Metal Cup Diffusion Bonding Process [for the Continuum Cup and TM Modular Cup] has been validated with a high degree of assurance". However, your validation results do not provide objective evidence that the diffusion bonding process is capable of consistently producing products that meet specified requirements. For example:

- A. As part of your firm's process validation of Titanium/Trabecular Metal Cup Diffusion Bonding, you conducted the operational qualification titled Challenge Testing at Critical Process Parameter Control Limits (b) (4) Revision 0, executed and reviewed on 12/10/2008). (b) (4) states, as part of the Procedure Steps for Bond Strength Worst Case

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 07/06/2011 - 07/22/2011*
	FEI NUMBER 1000220733

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Jeffery A. McCaulley, President, Zimmer Reconstructive**

FIRM NAME Zimmer Inc.	STREET ADDRESS 345 E. Main Street
CITY, STATE, ZIP CODE, COUNTRY Warsaw, IN 46580-2304	TYPE ESTABLISHMENT INSPECTED Medical Device

Challenge Test, that the "Ultimate soak conditions" are (b) (4) for each cycle. The operational qualification protocol calls for a total of (b) (4) heating cycles.

Your process validation results include furnace trend charts for each of the (b) (4) cycles, dated 9/26/2008 and 9/29/2008, which (b) (4). The soak temperature axis is labeled in (b) (4) °C increments, and the soak time axis is not clearly labeled. Your furnace trending chart is not adequate for its intended use of providing soak temperature readouts within ±5°C and soak time readouts within +0/-2.5 minutes. Additionally, your furnace trending charts are not adequate to determine the actual (i.e., quantified) soak time and soak temperature the test samples were held to, and whether or not these parameters fell within your predetermined acceptance criteria of (b) (4).

B. (b) (4) states, as part of the *Procedure Steps for Bond Strength Worst Case Challenge Test*, that the "Ultimate soak conditions" include a soak time of (b) (4) for each cycle.

The soak times for each of the (b) (4) cycles were documented in a *Furnace Master Heat Log*. In each case, the soak time was outside of the predetermined acceptance criterion (b) (4) minutes):

Furnace Asset #	Heat #	Date	Documented Soak Time	Conversion to Minutes
(b) (4)	(b) (4)	9/26/2008	4 hours	240 min
		9/29/2008	3 hours, 52 min	232 min

Your firm's *Final Validation/Qualification Report for Titanium/Trabecular Metal Cup Diffusion Bonding* (Project (b) (4) Revision 0), which was approved on 1/19/2009, lists protocol deviations under *Section 5.1*. Your documented soak times were not identified as deviations from your validation protocol.

C. The functions of the diffusion bonding furnaces used by your firm are controlled using (b) (4) software. Various "recipes" (i.e., programs) may be loaded into the software, depending on the needs of the process (e.g., heating rate). Your firm purportedly provided us with the printable output for the program used during your diffusion bonding process validation. The document does not indicate that the program was indeed used during your diffusion bonding validation, and your firm was unable to verify whether or not this was the case. Your firm could not provide adequate objective evidence documenting which (b) (4) software furnace program was used during your process validation.

D. The *Sampling Plan* for (b) (4) is stated as such: (b) (4)

Your firm's *Final Validation/Qualification Report for Titanium/Trabecular Metal Cup Diffusion Bonding* (Project (b) (4) Revision 0), which was approved on 1/19/2009 states, under *Summary*, that "In summary, the OQ sample parts, (b) (4) 80 mm (b) (4) parts and (b) (4) 78 mm TM Modular parts, passed the tensile strength requirement". Your firm's process validation protocol calls for a sample size of (b) (4) titanium alloy/Trabecular Metal hip cups, but only (b) (4)

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hip cups were used during the operational qualification phase of your process validation.

E. (b) (4) states, as part of the *Objective*, that (b) (4)  
(b) (4)  
(b) (4)

Although your firm's operational qualification protocol identified pressure as one of three worst-case conditions, your firm's management stated that pressure was not a challenged parameter during worst-case testing when executing the operational qualification phase of your process validation.

F. (b) (4) states, as part of the *Procedure Steps for Bond Strength Worst Case Challenge Test*, to (b) (4)  
(b) (4)

Zimmer Work Instruction (ZWI) (b) (4) titled (b) (4) *Vacuum Furnace Systems Operation in* (b) (4) Revision 4, effective 3/11/2011) is the current work instruction for loading the diffusion bonding furnace. According to the *Furnace Load Specifications* within (b) (4) the "Maximum quantity of product allowed" is (b) (4) pcs."

As part of your firm's process validation of *Titanium/Trabecular Metal Cup Diffusion Bonding*, you conducted the performance qualification titled *Process Capability Analysis* (Performance Qualification Project # (b) (4) Revision 0, executed and reviewed on 12/10/2008). The performance qualification *Procedure* states to (b) (4)  
(b) (4)

ZWI (b) (4) titled *Furnace Operations for Diffusion Bonding Trabecular Metal to Titanium (Ti-6Al-4V)* (Revision 3 effective 4/11/2008), states that Step 8 of the "Build Load" phase is to (b) (4)  
(b) (4) as defined in the validation." Management stated that (b) (4) hip cup fixtures would fit into this "defined work area."

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Despite that a production load may vary from 1 to greater than (b) (4) hip cup devices and that your firm's operational qualification protocol specified to (b) (4), there exists no evidence that your firm's process validation addressed or challenged load configuration as a process parameter when executing your process validation.

G. OQ (b) (4) states, as part of *Required Equipment*, that the (b) (4) "Furnace" with asset number (b) (4) was to be used during worst-case scenario testing (i.e., operational qualification).

Your firm's *Qualification/Validation Plan for Titanium/Trabecular Metal Cup Diffusion Bonding* (Project # (b) (4) Validation Plan Revision #1) was approved on 12/5/2008 and included (b) (4) bonding furnaces. These include the (b) (4) furnace, as well as (b) (4) other furnaces, which were manufactured by a different manufacturer (b) (4)

During operational qualification, your firm performed worst-case scenario testing to challenge your predetermined processing limits using the (b) (4) furnace. There is no documentation that the (b) (4) furnaces, which were included

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in your *Qualification/Validation Plan for Titanium/Trabecular Metal Cup Diffusion Bonding*, were considered during worst-case scenario testing. Processing limits for the (b) (4) furnaces were not challenged.

- H. Your firm's *Qualification/Validation Plan for Titanium/Trabecular Metal Cup Diffusion Bonding* (Project # (b) (4) Validation Plan Revision #1) was approved on 12/5/2008 and included (b) (4) bonding furnaces. According to management, the installation qualification (IQ) completion dates for each furnace are:

Asset #	Manufacturer	Model #	IQ Completion Date
(b) (4)			7/23/2004
			11/24/2004
			10/12/2007
			11/29/2007
			11/24/2008

Your firm's management stated that (1) the model numbers vary because the furnaces were purchased at different times, and (2) that they represent different versions of the diffusion bonding furnaces.

As part of your firm's process validation of *Titanium/Trabecular Metal Cup Diffusion Bonding*, you conducted the performance qualification titled *Process Capability Analysis* (Performance Qualification Project (b) (4) Revision 0, executed and reviewed on 12/10/2008). The performance qualification *Procedure* documents that the only furnaces used during performance qualification were those with asset numbers (b) (4). During performance qualification, no hip cup lots were processed by 3 of the (b) (4) furnaces included in your firm's *Qualification/Validation Plan for Titanium/Trabecular Metal Cup Diffusion Bonding*. Thus, there exists no objective evidence that the three omitted furnaces are capable of consistently producing products that meet your acceptance criteria.

- I. As part of your firm's process validation of *Titanium/Trabecular Metal Cup Diffusion Bonding*, you conducted the performance qualification titled *Process Capability Analysis* (Performance Qualification Project (b) (4) Revision 0, executed and reviewed on 12/10/2008). The performance qualification *Procedure* documents that the last load processed during performance qualification occurred on 11/4/2008.

The (b) (4) furnace with asset number (b) (4) was installed on 11/24/2008. Your firm's *Qualification/Validation Plan for Titanium/Trabecular Metal Cup Diffusion Bonding*, which was approved on 12/10/2008, does not document why another bonding furnace was added to the validation, nor does it rationalize why the process was not validated for the (b) (4) furnace with asset number (b) (4).

- J. Zimmer Engineering Specification (b) (4) titled *Trabecular Metal Diffusion Bonding Process Parameters for Titanium (Ti-6Al-4V)*, states that the maximum load size is (b) (4). Based on your memorandum dated 7/13/2011 and titled *Summary Table for Furnace Load Size Used for Process Qualification Project (b) (4)*, "The minimum number of pieces in a furnace load in the performance qualification was (b) (4) pieces. The maximum number of pieces in a furnace load in the performance qualification was (b) (4) pieces."

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Zimmer Work Instruction (ZWI) (b) (4) titled (b) (4) *Vacuum Furnace Systems Operation in (b) (4)* (Revision 4, effective 3/11/2011), is the current work instruction for loading the diffusion bonding furnace. According to the *Furnace Load Specifications*, the "Maximum quantity of product allowed" is (b) (4) pcs."

ZWI (b) (4) permits furnace loads to range from 1 to (b) (4) pieces; however, your diffusion bonding process is only performance qualified for furnace loads between (b) (4) pieces.

**PART B: TITANIUM ALLOY/TRABECULAR METAL HIP CUP REWORK PROCEDURE**

Your firm's Standard Operating Procedure (SOP) (b) (4) titled *Validation Master Plan* (Revision 2, effective 6/19/2009), was not fully implemented at its time of use. It defines validation as (b) (4). The Purpose of the procedure is "to define the methodology, activities, and deliverables required to assure that systems and processes are validated".

Your firm's Zimmer Work Instruction (ZWI) (b) (4) titled (b) (4) & *TM Modular Cup Post Bond Machining* (Revision 3, effective 4/22/2010) describes the procedure for machining the (b) (4) hip cup (also known as the *Continuum* hip cup, which is described in Part A) after undergoing the diffusion bonding process also described in Part A.

Per ZWI (b) (4) employees are permitted to perform mechanical rework on a *Continuum* hip cup in the event that the device fails the defined design specification for circularity. Specifically, if the hip cup is measured for circularity and found to be unacceptably "out of round," it is placed into a vice and mechanical force (i.e., compression) is applied, which physically deforms the hip cup into an acceptably round shape that meets the circularity specification. After this rework step, the device is checked to ensure that all other dimensions meet their respective design specifications. The number of hip cups your firm reworks during each production order is documented in the production order's respective Device History Record (DHR). However, specifically which individual hip cups are reworked is not documented and cannot be determined by reviewing your firm's DHRs. Your firm's management estimated that approximately 6% of all *Continuum* hip cups manufactured undergo the rework process.

According to discussion with management on 7/12/2011 and 7/13/2011, the rework process was validated according to Zimmer Research Report (ZRR) number (b) (4) titled *Effects of Bending (b) (4) Continuum Shells on the Substrate and the Porous Coating Bonding Interface*, which was approved on 1/29/2010. Your firm manufactures *Continuum* hip cups with varying diameters to accommodate a variety of physician and patient needs. Additionally, your firm manufactures *Continuum* hip cups in three unique screw hole configurations so that the physician may fix the hip cup to the patient's acetabulum as securely as possible:

- Uni-Hole (i.e., one screw hole)
- Cluster-Hole (i.e., three asymmetrically oriented screw holes)
- Multi-Hole (i.e., three symmetrically oriented screw holes)

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The scope of (b) (4) included *Continuum* hip cups with diameters ranging from 48 mm to 78 mm (in increments of 2 mm). For each diameter, all three screw hole configurations were also within the scope of the report. The report states that (b) (4)

(b) (4) However, the validation results documented in your report do not provide objective evidence that the *Titanium Alloy/Trabecular Metal* rework process is capable of consistently producing products that meet specified requirements. For example:

- A. Five identical, 48 mm-diameter cluster-hole *Continuum* cups were tested. Of these, zero had failed to meet the defined circularity specification prior to testing. The experimental setup for your process validation did not accurately simulate the scenario intended to be validated.
- B. Only one diameter and screw hole configuration (48 mm, Cluster-Hole) was tested during validation. Subsequently, these test results were compared against a Finite Element (FE) Model in an attempt to positively test the model's validity. More data points are necessary to definitively validate that the FE Model may be used to accurately predict the mechanical and material characteristics of reworked devices with diameters and screw hole configurations other than that which was physically tested.
- C. Zimmer Work Instruction (ZWI) (b) (4) titled (b) (4) & *TM Modular Cup Post Bond Machining* (Revision 3, effective 4/22/2010), permits multiple rework cycles, so long as compression axis remains constant for each cycle and deflection is no more than (b) (4). Material fatigue strength is not given consideration and not a challenged parameter during your process validation.
- D. Other pertinent parameters are not given consideration and are not challenged during your process validation, including:
  - a. Compression axis with respect to screw hole orientation and location
  - b. Heating rate during the diffusion bonding process, which may vary according to your firm's diffusion bonding procedures

**OBSERVATION 6**

Certain inspection, measuring, and test equipment is not suitable for its intended purposes.

Specifically,

The Purpose of your firm's most recent revision of Standard Operating Procedure (SOP) (b) (4) titled *Manufacturing Process Inspection System* (Revision 15, effective 6/30/2010), is to "Describe the procedure to perform quality inspections during the manufacturing process." Additionally, at least one Measurement Instruction Sheet (MIS) is associated with each product lot manufactured by your firm. The MIS sheet details each dimensional measurement that must be checked by your

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employees to determine whether or not design specifications are met. SOP (b) (4) delineates how your employees are to complete MIS sheets in order to perform in-process acceptance activities for products manufactured by your firm.

MIS sheets call for the use of a caliper, micrometer, and/or height gage to routinely perform dimensional measurements for many products manufactured by your firm, including the *Continuum* hip cup.

The *Continuum* hip cup is one component of your firm's *Continuum Acetabular System*. Your firm's indications for use state that:

- The system is indicated for primary or revision surgery in skeletally mature individuals for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses
- The system is intended for use either with or without bone cement in total hip arthroplasty

The *Continuum* hip cup is made up primarily of two components, which are married via the diffusion bonding process (see **Observation 5**):

- A *Trabecular Metal* "shell" (porous tantalum that is proximal to the patient's acetabulum when implanted)
- A *Titanium* "substrate" (titanium alloy that is distal to the patient's acetabulum when implanted)

Your firm manufactures the *Continuum* hip cup in (b) (4) broad phases:

(b) (4)

Your firm performs in-process acceptance activities after each of these phases. The *Continuum* hip cup dimensions measured using a caliper, micrometer, or height gage during such in-process activities are as follows:

(b) (4)	Dimension Measured	Instrument Used
(b) (4)		

According to your firm's management, the calibration specifications and resolution limits for your calipers, micrometers, and height gages are as follows:

Gage	Calibration Specification	Resolution
Caliper	(b) (4)	

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TYPE ESTABLISHMENT INSPECTED

Medical Device

Gage	Calibration Specification	Resolution
Micrometer	(b) (4)	
Height gage		

As shown above, the measurement precision of your firm's calipers, micrometers, and height gages is limited by the respective calibration specification. *The precision limitations of your measurement instruments do not allow your firm to definitively ensure that design specifications are being fulfilled in 11 of 11 Device History Records reviewed.* For example:

1. After machining the Tivanium substrate, your firm uses a caliper to verify that the flange height dimension is between (b) (4). According to your firm's management, your calipers read out to 1/10,000 of an inch (i.e., four decimal places). Suppose the measurement reads 0.2550 inches, and so it is deemed to be within your design specification. However, due to the precision limit of your firm's caliper, the actual flange height may in fact be 0.2560 inches. Your firm's most recent revision of Standard Operating Procedure (SOP) (b) (4), titled *Nonconformance/Deviation Report* (Revision 13, effective 4/1/2011), defines a nonconformance as "the failure of a product, process or Device History documentation to meet specified requirements." In this situation, your firm would incorrectly allow the Tivanium substrate component to "pass" this particular check, as opposed to deeming the part to be a nonconformance per SOP (b) (4).
2. After machining the Tivanium substrate, your firm uses a micrometer to verify that the boss diameter is between (b) (4). According to your firm's management, your micrometers read out to 1/10,000 of an inch (i.e., four decimal places). Suppose the measurement reads 0.4934 inches. According to the most recent revision of Zimmer Work Instruction (ZWI) (b) (4), titled *Numerical Rounding of Dimensional Measurement Results* (Revision 4, effective 1/23/2006), employees are to "Round the measurement to the same level of significance (same number of digits to the right of the decimal point) as the corresponding specification". In this case, the measurement would be rounded to 0.493 inches, and so it is deemed to be within your design specification. However, due to the precision limit of your firm's micrometer, the actual boss diameter may in fact be 0.4935 inches, which would subsequently be rounded to 0.494 inches. In this situation, your firm would incorrectly allow the Tivanium substrate component to "pass" this particular check, as opposed to deeming the part to be a nonconformance per SOP (b) (4).
3. After machining the final *Continuum* hip cup post-diffusion bonding, your firm uses a height gage to verify that the overall cup height is at least (b) (4). According to your firm's management, your height gages read out to 1/10,000 of an inch (i.e., four decimal places). Suppose the measurement reads 0.8360 inches, and so it is deemed to be within your design specification. However, due to the precision limit of your firm's height gage, the actual overall cup height may in fact be 0.8350 inches. In this situation, your firm would incorrectly allow the final *Continuum* hip cup to "pass" this particular check, as opposed to deeming the part to be a nonconformance per SOP (b) (4).

**RECORDS**

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**OBSERVATION 7**

The device history record does not demonstrate that the device was manufactured in accordance with the device master record.

Specifically,

The Purpose of your firm's most recent revision of Standard Operating Procedure (SOP) (b) (4) titled *Manufacturing Process Inspection System* (Revision 15, effective 6/30/2010), is to "Describe the procedure to perform quality inspections during the manufacturing process." Additionally, at least one Measurement Instruction Sheet (MIS) is associated with each product lot manufactured by your firm. The MIS sheet details each dimensional measurement that must be checked by your employees to determine whether or not design specifications are met. SOP (b) (4) delineates how your employees are to complete MIS sheets in order to perform in-process acceptance activities for products manufactured by your firm, including the *Continuum* hip cup.

The *Continuum* hip cup is one component of your firm's *Continuum Acetabular System*. Your firm's indications for use state that:

- The system is indicated for primary or revision surgery in skeletally mature individuals for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses
- The system is intended for use either with or without bone cement in total hip arthroplasty

The *Continuum* hip cup is made up primarily of two components, which are married via the diffusion bonding process (see Observation 5):

- A *Trabecular Metal* "shell" (porous tantalum that is proximal to the patient's acetabulum when implanted)
- A *Titanium* "substrate" (titanium alloy that is distal to the patient's acetabulum when implanted)

Your firm manufactures the *Continuum* hip cup in (b) (4) broad phases:

(b) (4)

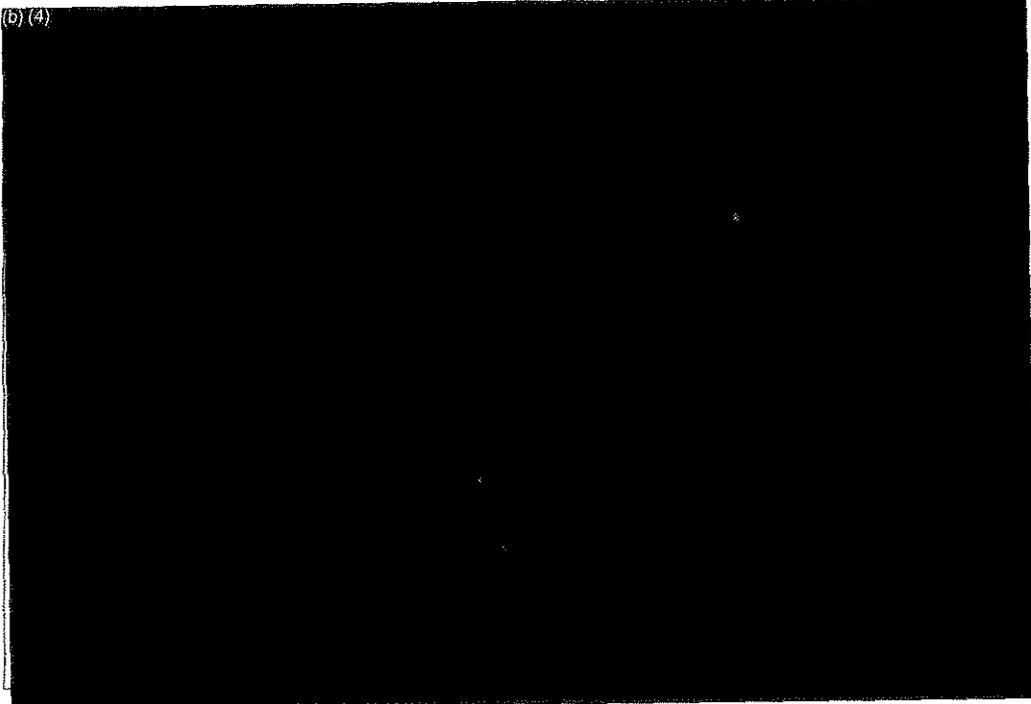
Your firm performs in-process acceptance activities after each of these phases. The *Continuum* hip cup dimensions that are measured quantitatively (i.e., as opposed to dimensions that are verified by a go/no go check) include:

(b) (4)

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**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 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		07/06/2011 - 07/22/2011*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FBI NUMBER
TO: Jeffery A. McCaulley, President, Zimmer Reconstructive		1000220733
FIRM NAME	STREET ADDRESS	
Zimmer Inc.	345 E. Main Street	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Warsaw, IN 46580-2304	Medical Device	



*In 11 of 11 Device History Records reviewed, your firm failed to document the actual dimensional measurements described above as evidence that your device was manufactured in accordance with the Device Master Record.*

Additionally, your firm performs "VERIFY PART: PRODUCT IDENTIFIERS" during inspection of the *Continuum* hip cup after diffusion bonding. This step involves a number of checks as defined by the part drawings and SOP (b) (4). Although your MIS sheet requires this step to be performed visually, one of these checks is a dimensional measurement of the device diameter, which your firm failed to document in 11 of 11 Device History Records reviewed as evidence that your device was manufactured in accordance with the Device Master Record.

Finally, upon machining the Titanium substrate for the *Continuum* hip cup, your MIS calls for visual checks of the flange/spherical radius junction and the boss/spherical radius junction, each of which have a tolerance of +/- (b) (4) inches. Such precision is impossible to achieve with the naked eye (*i.e.*, the dimension must be measured quantitatively). In 11 of 11 Device History Records reviewed, actual dimensional measurements for these design features were not documented as evidence that device was manufactured in accordance with the Device Master Record.

**ACCEPTANCE ACTIVITIES**

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**OBSERVATION 8**

Procedures for acceptance of incoming product have not been established.

Specifically,

Your firm's most recent revision of Zimmer Work Instruction (ZWI) <sup>(b) (4)</sup> titled *Receiving Inspection Procedure (Revision 14, effective 5/26/2010)*, has not been fully implemented. The *Purpose* of the procedure is to "provide an assessment system for dispositioning the quality of incoming finished devices and component materials that are used in a finished device". Additionally, your firm uses Inspection Instruction Sheets (IISs) to perform incoming product inspection. The IIS sheet details each feature that must be checked by your employees to determine whether or not the incoming product is suitable for use in a finished device. ZWI <sup>(b) (4)</sup> delineates how your employees are to complete IIS sheets in order to perform incoming product inspections. Form <sup>(b) (4)</sup> "GAGE/DATA COLLECTION SHEET" is used to document the inspection results. Per the ZWI <sup>(b) (4)</sup> *Guidelines*, "All orders where variable data can be collected requires the inspector to <sup>(b) (4)</sup> record the data on the Gage/Data Collection Sheet <sup>(b) (4)</sup>... For attribute data the inspector can record one Pass All for all samples." *In 2 of 2 Gage/Data Collection sheets reviewed, your firm failed to document all incoming product acceptance activities as evidence that such incoming product fulfills predetermined acceptance criteria for use in finished products.*

For example, step one of the IIS used for the inspection of incoming raw titanium alloy bar stock with description "2.75 DIA BAR TI 6AL 4V ELI" is termed "VERIFY PRODUCT IDENTIFIER" with description "VERIFY MAGNETIC CHECK". During this step, the inspector is required to use a magnet to test the magnetism of the bar stock. The respective Gage/Data Collection Sheet does not provide evidence that the required magnetic check was performed for raw titanium alloy bar stock. Your firm's management estimated that titanium alloy bar stock is used in approximately <sup>(b) (4)</sup> of finished products manufactured by your firm.

**OBSERVATION 9**

Procedures for the acceptance of in-process product have not been established.

Specifically,

Your firm's most recent revision of Standard Operating Procedure (SOP) <sup>(b) (4)</sup> titled *Manufacturing Process Inspection System (Revision 15, effective 6/30/2010)*, has not been fully implemented. The purpose of SOP <sup>(b) (4)</sup> is to "Describe the procedure to perform quality inspections during the manufacturing process." Additionally, at least one Measurement Instruction Sheet (MIS) is associated with each product lot manufactured by your firm. The MIS sheet details each dimensional measurement that must be checked by your employees to determine whether or not design specifications are met. SOP <sup>(b) (4)</sup> delineates how your employees are to complete MIS sheets in order to perform in-process acceptance activities for products manufactured by your firm.

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**TO: Jeffery A. McCaulley, President, Zimmer Reconstructive**

FIRM NAME Zimmer Inc.	STREET ADDRESS 345 E. Main Street
CITY, STATE, ZIP CODE, COUNTRY Warsaw, IN 46580-2304	TYPE ESTABLISHMENT INSPECTED Medical Device

Some machines used by your firm during manufacturing, such as mills and lathes, use cutting tools that wear down over time. Due to tool wear, these machines may no longer be able to adequately cut parts to meet your firm's design specifications. In cases of extreme wear, the cutting tool may break. In the event that your employees must replace the tool due to wear or breakage, your firm's management stated that the employee must perform in-process acceptance activities on the next part manufactured to ensure that design specifications are met. According to your firm's management, approximately (b) (4) machines used by your firm during manufacturing utilize disposable cutting tools.

The sampling plan for some dimensional measurements taken during in-process product inspection is "IST/LAST", as defined by the associated MIS sheet. An example such a dimensional measurement appears in the MIS for the *Continuum* hip cup.

The *Continuum* hip cup is one component of your firm's *Continuum Acetabular System*. Your firm's indications for use state that:

- The system is indicated for primary or revision surgery in skeletally mature individuals for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses
- The system is intended for use either with or without bone cement in total hip arthroplasty

The *Continuum* hip cup is made up primarily of two components, which are married via the diffusion bonding process (see **Observation 5**):

- A *Trabecular Metal* "shell" (porous tantalum that is proximal to the patient's acetabulum when implanted)
- A *Titanium* "substrate" (titanium alloy that is distal to the patient's acetabulum when implanted)

Your firm manufactures the *Continuum* hip cup in (b) (4) broad phases:  
(b) (4)

The MIS sheet delineating dimensional measurements that must be checked after final machining of the *Continuum* hip cup includes a check of (b) (4) which utilizes the "IST/LAST" sampling plan. For this particular check, the MIS instructs the employee to "Check part after a tool change". *In 11 of 11 Device History Records reviewed, your firm failed to document that in-process acceptance activities are performed after a tool change to ensure that design specifications are being fulfilled.*

**MANAGEMENT CONTROLS**

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Warsaw, IN 46580-2304	Medical Device	

**OBSERVATION 10**

Management with executive responsibility has not ensured that the quality policy is understood, implemented and maintained at all levels of the organization.

Specifically, as detailed in the preceding observations, management with executive responsibility has not ensured that as of the current inspection, the following components of the quality system have been fully implemented and maintained at all levels of your firm:

- Corrective and Preventive Actions (CAPA);
- Design Controls;
- Production and Process Controls (P&PC);
- Records; and
- Acceptance Activities.

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**Observation Annotations**

- |                                     |  |
|-------------------------------------|--|
| Observation 1: Under consideration. | Observation 2: Under consideration.              |
| Observation 3: Under consideration. | Observation 4: Under consideration.              |
| Observation 5: Promised to correct. | Observation 6: Promised to correct.              |
| Observation 7: Promised to correct. | Observation 8: Reported corrected, not verified. |
| Observation 9: Promised to correct. | Observation 10: Promised to correct.             |

**\* DATES OF INSPECTION:**

07/06/2011(Wed), 07/07/2011(Thu), 07/08/2011(Fri), 07/11/2011(Mon), 07/12/2011(Tue), 07/13/2011(Wed), 07/14/2011(Thu), 07/15/2011(Fri), 07/21/2011(Thu), 07/22/2011(Fri)

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