Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016 K061226 Page 1/2

Summary of Safety and Effectiveness

AUG 0 2 2006

Submitter:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person:

Patricia Jenks
Specialist, Corporate Regulatory Affairs
Telephone: (574) 371-8354
Fax: (574) 372-4605

Date:

July 26, 2006

Trade Name:

Zimmer *Trabecular Metal*™ Acetabular Revision System Cage

Common Name:

Acetabular Cage

Classification Name and Reference:

Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous, Uncemented
21 CFR § 888.3358

Predicate Device:

Burch/Schneider™ Reinforcement Cage, K960678, cleared May 3, 1996, manufactured by Zimmer GmbH (formerly Centerpulse Orthopedics Ltd.)

Device Description:

The Zimmer *Trabecular Metal* Acetabular Revision System Cage is a device intended to bridge the areas of acetabular bone loss in patients with acetabular bone deficiencies, such as pelvic defects and discontinuities. The cage is a metallic, dome-shaped, flanged acetabular component with multiple screw holes for adjunct intraoperative peripheral stabilization of revision shell constructs.

The cage is available in five sizes configured in both right and left versions along with either short or long flanges to meet various anatomical needs. It offers intraoperative flexibility of implant orientation/positioning to accommodate patient anatomies. The cage is fabricated from Commercially Pure (CP) Titanium.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Intended Use:	This device is intended for cemented use only as part of a layered construct and is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.
Comparison to Predicate Device:	Both the predicate and proposed devices are intended for revision hip surgeries to bridge the areas of acetabular bone loss in patients with acetabular bone deficiency.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Engineering evaluations were performed to verify that the performance of the device would be adequate for anticipated in vivo use. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2006

Ms. Patricia Jenks
Specialist, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K061226
Trade/Device Name: Trabecular Metal Acetabular Revision System Cage
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Codes: LPH
Dated: July 26, 2006
Received: July 27, 2006

Dear Ms. Jenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.S.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Indications for Use

510(k) Number (if known): K061226

Device Name:

Zimmer *Trabecular Metal*™ Acetabular Revision System Cage

Indications for Use:

This device is intended for cemented use only as part of a layered construct and is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061226

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2006

Ms. Patricia Jenks
Specialist, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K061226
Trade/Device Name: Trabecular Metal Acetabular Revision System Cage
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Codes: LPH
Dated: July 26, 2006
Received: July 27, 2006

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Indications for Use

510(k) Number (if known): K061226

Device Name:

Zimmer *Trabecular Metal*™ Acetabular Revision System Cage

Indications for Use:

This device is intended for cemented use only as part of a layered construct and is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____
(21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061226

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 24, 2006

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: PATRICIA JENKS

510(k) Number: K061226
Device: TRABECULAR METAL ACETABULAR REVISION SYSTEM CAGE

Extended Until: 14-AUG-2006

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

July 21, 2006

Office of Device Evaluation
Document Control Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Dear Sir or Madam:

SUBJECT: *Zimmer® Trabecular Metal™* Acetabular Revision System Cage-K061226

The subject premarket notification was received by FDA on May 2, 2006. We received a letter on June 23, 2006, from FDA requesting additional information. In order to respond to FDA's request for additional information, we will require further time to complete our response and hereby ask for an additional 30-day extension.

If you have any questions, please contact me by phone at (574) 371-8354, by fax at (574) 372-4605, or by email at trish.jenks@zimmer.com

Thank you for your consideration in this matter.

Sincerely,

Patricia E. Jenks
Specialist, Regulatory Affairs
Zimmer, Inc.

K16

pej/me
RA076506K.LT

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

CDRH Submission Cover Sheet

Date of Submission:	FDA Document Number:
July 21, 2006	K061226

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☒ Original submission: ☒ Traditional ☐ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):
IDE	**Humanitarian Device Exemption**	**Class II Exemption**	**Evaluation of Automatic Class III Designation**	**Other Submission**
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B — Applicant or Sponsor

Company/Institution name: Zimmer, Inc.			Establishment registration number: 1822565
Division name (if applicable): N/A			Phone number (include area code): 574-372-4485
Street address: P.O. Box 708			FAX number (include area code): 574-372-4605
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Toni Kingsley, Ph.D., RAC			
Contact Title: Vice President, Corporate Regulatory Affairs and Compliance		Contact e-mail address: toni.kingsley@zimmer.com	

Section C — Submission Correspondent (If Different from Above)

Company/Institution name: Zimmer, Inc.			Establishment registration number 1822565
Division name (if applicable): N/A			Phone number (include area code): 574-371-8354
Street address: P.O. Box 708			FAX number (include area code): 574-372-4605
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Patricia Jenks			
Contact Title: Specialist, Corporate Regulatory Affairs		Contact e-mail address: trish.jenks@zimmer.com	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Section D1 — Reason for Submission -- PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Change in design, component or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Reponse to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):

Section D2 — Reason for Submission -- IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ Other reason (specify):

Section D3 — Reason for Submission – 510(k)

- ☐ New device
- ☐ Additional or expanded indications
- ☒ Other reason (specify): Extension of Time Request
- ☐ Change in technology
- ☐ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 LPH	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K960678	1 *Burch/Schneider*™ Reinforcement Cage	1 Zimmer GmbH- (formerly Centerpulse Orthopedics Ltd.)
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F — Product Information – Applicable to All Applications

Common or usual name or classification name: Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous, Uncemented

Trade or proprietary or model name	Model number
1 *Trabecular Metal*™ Acetabular Revision System Cage	1 See Exhibit G
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 K003181	2 K050937	3 K051516	4	5	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☐ Human trials

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Section G — Product Classification – Applicable to All Applications

Product code:	C.F.R. Section	Device class:
LPH	888.3358	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Orthopedics/87		

Indications (from labeling):

This device is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H — Manufacturing/Packaging/Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA Establishment registration number: (b)(4) [redacted]	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract manufacturer ☐ Repackager/Relabeler

(b)(4) [redacted]

☒ Original ☐ Add ☐ Delete	FDA Establishment registration number: (b)(4) [redacted]	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract manufacturer ☐ Repackager/relabeler

(b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2006

Ms. Patricia Jenks
Specialist, Corporate Regulatory Affairs
Zimmer, Inc.
P. O. Box 708
Warsaw, Indiana 46581-0708

Re: K061226
Trade/Device Name: Zimmer Trabecular Metal Acetabular Revision System Cage
Dated: May 02, 2006
Received: May 02, 2006

Dear Ms. Jenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies:

(b)(4) Deficiencies

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

(b)(4) Deficiencies

[redacted]

The deficiencies identified above represent issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving this issue. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve this issue, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Ronald P. Jean, Ph.D. at (301) 594-2036, extension 181. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson, M.S.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ms. Patricia Jenks
Specialist, Corporate Regulatory Affairs
Zimmer, Inc.
P. O. Box 708
Warsaw, Indiana 46581-0708

Re: K061226
Trade/Device Name: Zimmer Trabecular Metal Acetabular Revision System Cage
Dated: May 02, 2006
Received: May 02, 2006

Dear Ms. Jenks:

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(b)(4) Deficiencies

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

(b)(4) Deficiencies

[redacted]

The deficiencies identified above represent issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving this issue. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve this issue, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Ronald P. Jean, Ph.D. at (301) 594-2036, extension 181. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

FILE COPY

45

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ 410	Jean	06/13						
HFZ 410	[illegible]	6/13						

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.

f/t: RPJ 06/13/2006

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1515, Released by CDRH on 09-12-2016

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 03, 2006

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: PATRICIA JENKS

510(k) Number: K061226
Received: 02-MAY-2006
Product: TRABECULAR METAL ACETABULAR REVISION SYSTEM CAGE

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016 K061226

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ZIMMER INC
P O BOX 708
WARSAW IN 46581-0708
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
810550219

2. CONTACT NAME
Patricia Jenks

2.1 E-MAIL ADDRESS
trish.jenks@zimmer.com

2.2 TELEPHONE NUMBER (include Area code)
574-371-8354

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
NO DATA

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4)

23-Mar-2006

Form FDA 8601 (08/2003)

Close Window

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

CDRH Submission Cover Sheet

Date of Submission: May 2, 2006	FDA Document Number:

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☒ Original submission: ☒ Traditional ☐ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):
IDE	**Humanitarian Device Exemption**	**Class II Exemption**	**Evaluation of Automatic Class III Designation**	**Other Submission**
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B — Applicant or Sponsor

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-372-4485	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Toni Kingsley, Ph.D.			
Contact Title: Vice President, Corporate Regulatory Affairs and Compliance		Contact e-mail address: toni.kingsley@zimmer.com	

Section C — Submission Correspondent (If Different from Above)

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-371-8354	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Patricia Jenks			
Contact Title: Specialist, Corporate Regulatory Affairs		Contact e-mail address: trish.jenks@zimmer.com	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Section D1 — Reason for Submission -- PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Reponse to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Other reason (specify):
- ☐ Change in design, component or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Change in ownership
- ☐ Change in correspondent

Section D2 — Reason for Submission -- IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting

Section D3 — Reason for Submission – 510(k)

- ☒ New device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):
- ☐ Change in technology
- ☐ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 LPH	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K960678	1 *Burch/Schneider*™ Reinforcement Cage	1 Zimmer GmbH- (formerly Centerpulse Orthopedics Ltd.)
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F Product Information – Applicable to All Applications

Common or usual name or classification name: Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous, Uncemented

Trade or proprietary or model name	Model number
1 *Trabecular Metal*™ Acetabular Revision System Cage	1 See Exhibit G
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 K003181	2 K050937	3 K051516	4	5	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☐ Human trials

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Section G — Product Classification – Applicable to All Applications

Product code:	C.F.R. Section	Device class:
LPH	888.3358	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Orthopedics/87		

Indications (from labeling):

This device is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H — Manufacturing/Packaging/Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA Establishment registration number: (b)(4) [redacted]	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract manufacturer ☐ Repackager/Relabeler

(b)(4) [redacted]

☒ Original ☐ Add ☐ Delete	FDA Establishment registration number: (b)(4) [redacted]	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract manufacturer ☐ Repackager/relabeler

(b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Traditional 510(k) Premarket Notification

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- **Section 514 Compliance** 10
- **Summary of Safety and Effectiveness** 10
- **Device Description** 10
  - **Overview** 10
  - **Indications for Use** 11
  - **Predicate Device(s)** 12
  - **Substantial Equivalence Comparison** 12
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  - **Packaging** 12
  - **Labeling** 13
  - **Sterilization** 13

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Traditional 510(k) Premarket Notification

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Exhibit I -- Performance Testing 36

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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zimmer

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

May 2, 2006

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

K-2

Dear Sir or Madam:

Subject: Traditional 510(k) Premarket Notification – Zimmer *Trabecular Metal*™ Acetabular Revision System Cage

As required by Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, FDA Modernization Act of 1997 (FDAMA) and in accordance with Title 21 of the Code of Federal Regulations (CFR) Part 807, subpart E, the above noted premarket notification is hereby submitted to the Food and Drug Administration (FDA). As required by 21 CFR 807.90(c), this document is submitted in duplicate. A CD-ROM with identical content to the paper submission is also included for your convenience.

These devices have not been previously submitted to FDA for identical or different indications, are not currently being reviewed for different indications by the same or different branch within ODE, and have not been previously cleared by FDA for different indications.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-8354, by e-mail at trish.jenks@zimmer.com or fax at (574) 372-4605.

Sincerely,

Patricia Jenks
Specialist, Corporate Regulatory Affairs

tj/me
Enclosure

OR II 68

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Zimmer *Trabecular Metal*™ Acetabular Revision System Cage

Traditional 510(k) Submission

zimmer

P.O. Box 708
Warsaw, IN 46581-0708

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Truthful and Accurate Statement

The truthful and accurate statement is presented in **Exhibit A.**

Device Name

Zimmer *Trabecular Metal*™ Acetabular Revision System Cage

Section 514 Compliance

Section 514 of the Act does not apply to this type of device at this time

Summary of Safety and Effectiveness

A summary of information regarding safety and effectiveness for the proposed device is presented in **Exhibit B.**

Device Description

Overview

The Zimmer *Trabecular Metal* Acetabular Revision System Cage is a device intended to bridge the areas of acetabular bone loss in patients with acetabular bone deficiencies, such as pelvic defects and discontinuities. The cage is a metallic, dome-shaped, flanged acetabular component with multiple screw holes for adjunct intraoperative peripheral stabilization of revision shell constructs (see Figure 1).

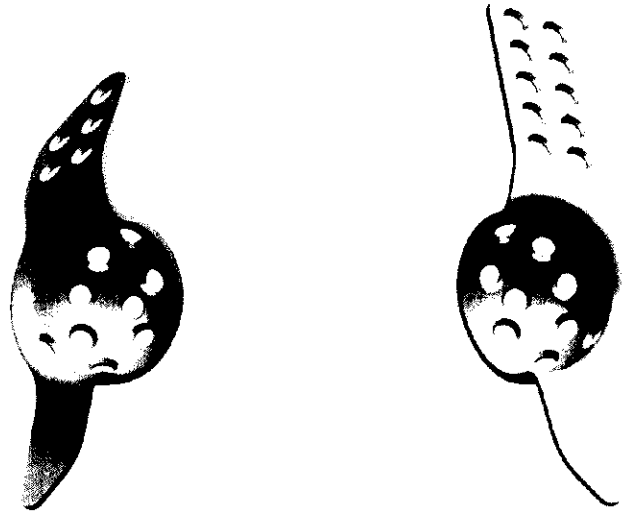

Figure 1 –
Representative cage graphics of right and left versions with short and long flanges

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

The cage is designed to be layered between commercially available *Trabecular Metal* Acetabular Revision Shells (K003181, cleared November 7, 2000 and K050937, cleared May 11, 2005) and polyethylene acetabular liners (K051516, cleared July 27, 2005) using bone cement fixation. The cage is intended to aid in initial stabilization of the *Trabecular Metal* shell until biological fixation can occur.

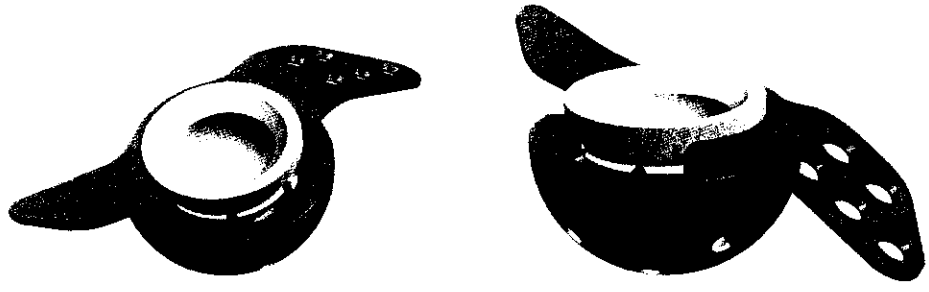

Figure 2 –
Representative graphics of revision shell, cage, and polyethylene liner constructs

The dome of the proposed cage features multiple screw holes which can be aligned with the screw holes of the *Trabecular Metal* Acetabular Revision Shell to allow for optional additional fixation. The cage is available with either a superior short or long flange employing 5 or 10 screw holes for attachment to the ilium. The superior flange has bending flexibility which allows it to be shaped to fit the contour of the ilium by use of a cage provisional as a template. An inferior flange without screw holes is provided for use as an ischial spike. The inferior flange is designed to provide additional stability via insertion into a surgically prepared ischial notch.

The cage is available in five sizes configured in both right and left versions along with either short or long flanges to meet various anatomical needs. It offers intraoperative flexibility of implant orientation/positioning to accommodate various patient anatomies. The cage is fabricated from Commercially Pure (CP) Titanium.

Indications for Use

This device is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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See **Exhibit C** for the Indications for Use.

Predicate Device(s)

The predicate and design basis for the proposed device is the *Burch/Schneider*™ Reinforcement Cage, K960678, cleared May 3, 1996, manufactured by Zimmer GmbH (formerly Centerpulse Orthopedics Ltd.). A copy of the substantial equivalence letter is presented in **Exhibit D**.

Substantial Equivalence Comparison

See **Exhibit E** for a comparison table between the predicate and proposed *Trabecular Metal* Acetabular Revision System Cage.

Engineering Drawings/Dimensions

Representative engineering drawings for the proposed *Trabecular Metal* Acetabular Revision System Cage are included in **Exhibit F**.

Item Numbers

All item numbers for the proposed *Trabecular Metal* Acetabular Revision System Cage implants are listed in **Exhibit G**.

Materials

The material, CP Titanium, is identical to that commonly used for existing, clinically proven orthopedic implants.

Surgical Instrumentation Unique to the Device

Aside from standard Total Hip Arthroplasty instrumentation, single-use aluminum provisionals have been designed for use with this system.

Packaging

Package Design

The product is placed into a nylon/polyethylene pouch which is heat sealed with a peelable seal. This sealed pouch is then placed into another nylon/polyethylene pouch and heat sealed creating a double barrier. Sterile package protection is afforded by a third, protective pouch, also a nylon/polyethylene pouch and a solid bleach sulfate folding carton and shrink film.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Sterile Package Materials

The nylon/polyethylene laminated pouch consists of 15 microns (0.0006 inch) of oriented polyamide film adhesion laminated to 60 microns (0.0024 inch) of virgin Low Density Polyethylene film.

Labeling

Sample labels for the proposed *Trabecular Metal* Acetabular Revision System Cage implants are presented in **Exhibit H**, along with the draft package insert.

Exhibit H also contains the draft text for the *Trabecular Metal* Acetabular Revision System Cage surgical technique.

Sterilization

These devices are provided sterile via gamma irradiation. The dose for sterilization is 25 to 40 kilograys (kGy). The validation method for the dose setting validation is VDmax (per AAMI TIR 27:2001).

Resterilization

Resterilization of this device is specifically not recommended.

Biocompatibility

The material used in this device meets or exceeds ASTM standards, is common to orthopedic products today, and has a demonstrated safe clinical history.

Color Additives

This device does not have color additives. No additional biocompatibility testing is required.

Pyrogenicity

This device is not labeled as pyrogenic. Per USP XXIII (161), requirements for specified endotoxin levels do not apply to orthopaedic implants.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Performance Testing

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Specialist, Corporate Regulatory Affairs of Zimmer, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____
(Signature)

Patricia Jenks
(Typed Name)

5/1/06
(Date)

_____
(Premarket Notification [510(k)] Number)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Patricia Jenks Specialist, Corporate Regulatory Affairs Telephone: (574) 371-8354 Fax: (574) 372-4605
Date:	May 2, 2006
Trade Name:	Zimmer *Trabecular Metal*™ Acetabular Revision System Cage
Common Name:	Acetabular Cage
Classification Name and Reference:	Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous, Uncemented 21 CFR § 888.3358
Predicate Device:	*Burch/Schneider*™ Reinforcement Cage, K960678, cleared May 3, 1996, manufactured by Zimmer GmbH (formerly Centerpulse Orthopedics Ltd.)
Device Description:	The Zimmer *Trabecular Metal* Acetabular Revision System Cage is a device intended to bridge the areas of acetabular bone loss in patients with acetabular bone deficiencies, such as pelvic defects and discontinuities. The cage is a metallic, dome-shaped, flanged acetabular component with multiple screw holes for adjunct intraoperative peripheral stabilization of revision shell constructs. The cage is available in five sizes configured in both right and left versions along with either short or long flanges to meet various anatomical needs. It offers intraoperative flexibility of implant orientation/positioning to accommodate patient anatomies. The cage is fabricated from Commercially Pure (CP) Titanium.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Intended Use:	This device is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.
Comparison to Predicate Device:	Both the predicate and proposed devices are intended for revision hip surgeries to bridge the areas of acetabular bone loss in patients with acetabular bone deficiency.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Engineering evaluations were performed to verify that the performance of the device would be adequate for anticipated in vivo use. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Indications for Use

510(k) Number (if known):

Device Name:

Zimmer *Trabecular Metal*™ Acetabular Revision System Cage

Indications for Use:

This device is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 1996

RECEIVED
MAY 10 1996

Mr. Sam Mirza
Regulatory Affairs Specialist
Intermedics Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K960678
Burch/Schneider Reinforcement Cage
Regulatory Class: II
Product Code: JDI
Dated: February 15, 1996
Received: February 16, 1996

Dear Mr. Mirza:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Kimber C. Richter, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

510(k) Number (if known): Unknown K960678

Device Name: Burch/Schneider Antiprotrusio Cage

Indications For Use:

Specific Diagnostic Indications

The Burch/Schneider Reinforcement Cage is intended to bridge the areas of acetabular bone loss in patients with acetabular bone deficiency. In addition, the Burch/Schneider Reinforcement Cage, like the predicate devices, is intended to provide support for an all polyethylene acetabular implant in a cemented application.

Diagnostic indications for use of this device include, but are not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery.

The general indications associated with the use of Burch/Schneider Reinforcement Cage in total hip arthroplasty include:

1. Advanced joint destruction resulting from degenerative, posttraumatic or rheumatoid arthritis,

2. Fracture or avascular necrosis of the femoral head,

3. Failed previous surgery, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty and total hip replacement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR Over-The-Counter Use** _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K960678

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Substantial Equivalence Comparison between the Predicate and Proposed Device

Parameter	Identical, Similar or Different?	Similarities and Differences
Indications for use	Similar	• Indications for Use are similar for both the predicate and proposed devices. Both are indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement. • The proposed device is not indicated for fracture or avascular necrosis of the femoral head.
Design	Similar	• The predicate device is fixed directly into the natural acetabulum using cement fixation and optional screw fixation; whereas, the proposed implant is layered between previously cleared *Trabecular Metal* Acetabular Revision Shells and polyethylene liners using bone cement fixation with additional optional screw fixation. This proposed device is intended to aid in initial stabilization of the *Trabecular Metal* shell until biological fixation can occur. • The design of the predicate and the proposed devices is similar in that both cages are offered in right and left configurations and both feature superior and inferior flanges, screw holes for additional fixation, and a variety of sizes to address varying patient anatomies.
Materials	Identical	• Both the predicate and proposed cages are manufactured from Commercially Pure Titanium.
Sterility	Identical	• Both the predicate and proposed devices are sterilized by gamma irradiation.
Mechanical safety	Identical	• Both the predicate and proposed devices have been evaluated for safety (risk analysis) and require correct surgical technique to obtain a satisfactory surgical outcome.
Compatibility with the environment and/or other devices	Identical	• Both the predicate and proposed devices are excluded under 21 CFR § 25.34 (g), "Devices and Electronic Products." • Appropriate warnings for compatibility with other devices are included in the package insert.

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(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

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Zimmer *Trabecular Metal*™ Acetabular Revision System (TMARS) Cage Item Numbers

Description	Item Number
TMARS short flange cage 56/58/60 shell/48 liner right	00-7123-056-48
TMARS short flange cage 62/64 shell/54 liner right	00-7123-062-54
TMARS short flange cage 66/68/70 shell/58 liner right	00-7123-066-58
TMARS short flange cage 72/74 shell/64 liner right	00-7123-072-64
TMARS short flange cage 76/78/80 shell/68 liner right	00-7123-076-68
TMARS short flange cage 56/58/60 shell/48 liner left	00-7124-056-48
TMARS short flange cage 62/64 shell/54 liner left	00-7124-062-54
TMARS short flange cage 66/68/70 shell/58 liner left	00-7124-066-58
TMARS short flange cage 72/74 shell/64 liner left	00-7124-072-64
TMARS short flange cage 76/78/80 shell/68 liner left	00-7124-076-68
TMARS long flange cage 56/58/60 shell/48 liner right	00-7125-056-48
TMARS long flange cage 62/64 shell/54 liner right	00-7125-062-54
TMARS long flange cage 66/68/70 shell/58 liner right	00-7125-066-58
TMARS long flange cage 72/74 shell/64 liner right	00-7125-072-64
TMARS long flange cage 76/78/80 shell/68 liner right	00-7125-076-68
TMARS long flange cage 56/58/60 shell/48 liner left	00-7126-056-48
TMARS long flange cage 62/64 shell/54 liner left	00-7126-062-54
TMARS long flange cage 66/68/70 shell/58 liner left	00-7126-066-58
TMARS long flange cage 72/74 shell/64 liner left	00-7126-072-64
TMARS long flange cage 76/78/80 shell/68 liner left	00-7126-076-68

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TRABECULAR METAL™ ACETABULAR REVISION SYSTEM CAGE

Carefully read all instructions and be familiar with the surgical technique prior to use.

- **Zimmer has not tested the safety or effectiveness of this device for use in combination with non-Zimmer products or components. If surgeons elect to assemble and implant a construct that includes components not manufactured or distributed by Zimmer, they do so in reliance on their own clinical judgment and should so inform their patients.**

- **Due to the acquisition of pre-existing product lines, Zimmer has initiated a testing program to evaluate the compatibility of this device with implants and components made or distributed by all Zimmer companies, which include Zimmer GmbH (previously Centerpulse Orthopedics Ltd.), Zimmer Trabecular Metal Technology, Inc. (previously Implex Corp.), Zimmer U.K. Ltd., and Zimmer Austin, Inc. (previously Centerpulse Orthopedics, Inc.). Only authorized combinations should be used. To determine whether this device has been authorized for use in a proposed combination, please contact your Zimmer sales representative or visit the Zimmer website: www.productcompatibility.zimmer.com. A printout of the website information can also be obtained by calling Zimmer, Inc. Customer Service, 1-800-348-2759 (U.S.) or the local international access code +1-574-372-4999 (outside the U.S.).**

DESCRIPTION

The *Trabecular Metal* Acetabular Revision System Cage is a metallic dome-shaped, flanged acetabular component with multiple screw holes for adjunct intraoperative peripheral stabilization of revision shell/augment constructs. The cage is designed to be layered between a *Trabecular Metal* acetabular revision shell and a polyethylene acetabular liner using cement fixation. Additional optional screw fixation is available for the cage and shell. This device is intended to aid in initial stabilization of the *Trabecular Metal* shell until biological fixation can occur. The cage is available in right and left versions and with short and long flanges to meet various anatomical needs. The cage material is Commercially Pure (CP) Titanium.

INDICATIONS

This device is indicated for patients with conditions of, but not limited to:

- Acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery.
- Advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis.
- Failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

INFORMATION FOR USE

- Use only instruments specifically designed for use with this device to help ensure accurate surgical implantation, soft tissue balancing, and evaluation of hip function.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

CONTRAINDICATIONS

- Contraindications include:
  - Osteoradionecrosis
  - Skeletal immaturity
  - Any neuromuscular disease in the affected limb
  - Systemic or local infection

WARNINGS

- **DO NOT REVERSE BEND FLANGES OF THE *TRABECULAR METAL* ACETABULAR REVISION SYSTEM CAGE.**
- For safe and effective use of this implant, the Surgical Technique for the device should be consulted and carefully followed.
- This device is for single patient use only. Never reuse an implant. Although it may appear undamaged, previous stresses may have created imperfections that could reduce service life of the implant.
- Do not use any component if damage is found or caused during setup or insertion.
- Where there is loss of, or insufficient, acetabular bone stock, bone grafting or other adjunctive reinforcement procedures to provide socket support and cup containment are recommended.
- Stems with protruding features (i.e., collared stems, stems with trochanteric buildup) can increase the potential of metal-to-metal impingement and should be avoided if other alternatives are available.
- Patient physical activity can result in post-operative loosening, wear, and/or fracture of the hip implant.

PRECAUTIONS

- Continued surveillance for new or recurrent sources of infection should be continued as long as the device is in place.
- Do not use implant components to perform a trial reduction of the hip. Do not mate provisionals with implants.
- Ensure that the screw heads are properly seated. Use a 3.2 mm diameter drill prior to insertion of the compatible 6.5 mm diameter screws (6624, 6250, 03147, 42.19, and 00118 series). Avoid penetration beyond the inner cortex of the pelvis when drilling screw holes and inserting screws.
- Placing screws in the posterior inferior and posterior superior quadrants of the acetabulum may reduce the risk of injury to vascular or neurological structures. A wall chart illustrating these zones is available through your Zimmer representative.
- Appropriate placement of the component helps to avoid unintended loading of the component and may improve service life of the construct.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

ADVERSE EFFECTS

- The following adverse effects have been reported:
  - Peripheral neuropathies
  - Deep wound infections
  - Perforation of the acetabulum or femur
  - Heterotopic bone formation[1]
  - Metal sensitivity[2]
  - Wear
  - Inflammatory reactions and osteolysis[3]
  - Fatigue fracture
  - Vascular complications
  - Trochanteric problems
  - Subclinical nerve damage
  - Corrosion of metal implants
  - Early or late loosening of components of total hip arthroplasty
  - Pelvic, femoral, or acetabular fractures
  - Disassembly of modular components[4,5]

STERILITY

This device is provided sterile by prior exposure to gamma irradiation (indicated by the "Sterile-R" symbol on the labeling) and remain sterile as long as the package integrity has not been violated. Inspect each package prior to use and do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened, the component must be used or discarded.

RESTERILIZATION INFORMATION

Resterilization of this device is not recommended.

PATIENT COUNSELING INFORMATION

Complications and/or failure of total hip prostheses[6-9] are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or with patients who fail to follow through with the required rehabilitation program. Physical activity can result in loosening, wear, and/or fracture of the hip implant. The prospective implant patient must be counseled about the capabilities of the implant and the impact it will have on his or her lifestyle. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities and about the possibility that the implant or its components may wear out, fail, or need to be replaced. The implant may not, and is not guaranteed to, last the rest of the patient's life, or any specified length of time. Because prosthetic joints are not as strong, reliable, or durable as a natural, healthy joint, all prosthetic hips may need to be replaced at some point.

REFERENCES

References to relevant literature (see superscripts) may be obtained by calling the Zimmer Regulatory Affairs Department at 1-800-613-6131. For calls outside the USA, call the local international access code +1-574-267-6131.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Rx only

CE
0123

Manufactured by:
Zimmer, Inc.
1800 West Center Street
Warsaw, Indiana 46580
USA

Authorized Representative:
Zimmer U.K. Ltd.
9 Lancaster Place
South Marston Park
Swindon, SN3 4FP, UK

Rev. - March 2006
Printed in U.S.A.
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87-6203-750-01

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Summary for REF: 00-7125-056-48 Version: 00
Printed: feers at BAAL448A on 16.03.06 - 01:43 PM

Product Label

C.P. Titanium (Protasul®-Ti) ISO 5832-2

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

REF 00-7125-056-48 EDI: 00712505648
Trabecular Metal™
TM™ Acetabular Revision System
Long Flange Cage, right, cemented 56/58/60-48

STERILE R 2011-02

	CEMENTED	CAGE	56/58/60-48

47247 - v00

+H844007125056481/11059DUMMYC067

Bar Code Label

REF 00-7125-056-48 EDI: 00712505648
LOT DUMMY Qty. 001
TM™ Acetabular Revision System Long Flange Cage, right, cemented 56/58/60-48

+H844007125056481/11059DUMMYC067

TM™ Acetabular Revision System Stützschale lang, rechts, zementiert 56/58/60-48
TM™ Acetabular Revision System Armature platte longe, droite, cimentée 56/58/60-48
TM™ Acetabular Revision System Armatura aletta lunga, destra, cementato 56/58/60-48
TM™ Acetabular Revision System Cótilo aleta larga, derecha, cementado 56/58/60-48

Protasul®-Ti ISO 5832-2

CE 0123 Rx only STERILE R 2011-02 2006-03

Zimmer, Inc., Warsaw, IN 46580 U.S.A. / www.zimmer.com

EC REP Authorized EU Representative: Zimmer U.K. Ltd. Swindon, SN3 4FP, UK

25960v02 - LB1v00

Translation Label

CE 0123 Rx only STERILE R 2011-02 2006-03

Zimmer, Inc., Warsaw, IN 46580 U.S.A. / www.zimmer.com

EC REP Authorized EU Representative: Zimmer U.K. Ltd., Swindon SN3 4FP UK

REF 00-7125-056-48 EDI: 00712505648
LOT DUMMY Qty. 001

TM™ Acetabular Revision System
Stützschale lang, rechts, zementiert 56/58/60-48

TM™ Acetabular Revision System
Armature platte longe, droite, cimentée 56/58/60-48

TM™ Acetabular Revision System
Armatura aletta lunga, destra, cementato 56/58/60-48

TM™ Acetabular Revision System
Cótilo aleta larga, derecha, cementado 56/58/60-48

25960v01 - LB1v00

Patient Chart Sticker

REF 00-7125-056-48 EDI: 00712505648
LOT DUMMY Exp. 2011-02
TM™ Acetabular Revision System Long Flange Cage, right, cemented 56/58/60-48
C.P. Titanium (Protasul®-Ti) ISO 5832-2

+H844007125056481/11059DUMMYC067

Zimmer, Inc., Warsaw, IN 46580 U.S.A. / www.zimmer.com

25955v01 - LB1v00

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red	Right Green	Cemented Yellow	Uncemented Blue	Metasul® Magenta	Cerasul® Grey

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CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Summary for REF: (b)(4) **Version:** (b
Printed: feers at (b)(4) on 16.03.06 - 01:43 PM)

Product Label

C.P. Titanium (Protasul®-Ti) ISO 5832-2

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

REF 00-7126-056-48 EDI: 0071260648
Trabecular Metal™
TM™ Acetabular Revision System
Long Flange Cage, left, cemented 56/58/60-48

STERILE R 2011-02

◄ LEFT	CEMENTED	CAGE	56/58/60-48

+H44007126056481/11059DUMMYC068

Bar Code Label

REF 00-7126-056-48 EDI: 0071260648
LOT DUMMY Qty. 001
TM™ Acetabular Revision System Long Flange Cage, left, cemented 56/58/60-48
+H44007126056481/11059DUMMYC068
TM™ Acetabular Revision System Stützschale lang, links, zementiert 56/58/60-48
TM™ Acetabular Revision System Armature platte longe, gauche, cimentée 56/58/60-48
TM™ Acetabular Revision System Armatura aletta lunga, sinistra, cementato 56/58/60-48
TM™ Acetabular Revision System Cótilo aleta larga, izquierdo, cementado 56/58/60-48
CE 0123 Rx only STERILE R 2011-02 2006-03
Zimmer, Inc., Warsaw, IN 46580 U.S.A. / www.zimmer.com
EC REP Authorized EU Representative: Zimmer U.K. Ltd. Swindon SN3 4FP UK

Translation Label

CE 0123 Rx only STERILE R 2011-02 2006-03
Zimmer, Inc., Warsaw, IN 46580 U.S.A. / www.zimmer.com
EC REP Authorized EU Representative: Zimmer U.K. Ltd. Swindon SN3 4FP UK

REF 00-7126-056-48 EDI: 0071260648
LOT DUMMY Qty. 001
TM™ Acetabular Revision System
Stützschale lang, links, zementiert 56/58/60-48

TM™ Acetabular Revision System
Armature platte longe, gauche, cimentée 56/58/60-48

TM™ Acetabular Revision System
Armatura aletta lunga, sinistra, cementato 56/58/60-48

TM™ Acetabular Revision System
Cótilo aleta larga, izquierdo, cementado 56/58/60-48

25960v01 - LB1v00

Patient Chart Sticker

REF 00-7126-056-48 EDI: 0071260648
LOT DUMMY Exp 2011-02
TM™ Acetabular Revision System Long Flange Cage, left, cemented 56/58/60-48
C.P. Titanium (Protasul®-Ti) ISO 5832-2
+H44007126056481/11059DUMMYC068
Zimmer, Inc., Warsaw, IN 46580 U.S.A. / www.zimmer.com 25960v01 - LB1v00

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red	Right Green	Cemented Yellow	Uncemented Blue	Metasul® Magenta	Cerasul® Grey

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CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

TM Acetabular Revision System Technique - 2/20/06

Trabecular Metal™ Acetabular Revision System Cage

Surgical Technique

(circle Z)
Zimmer
Confidence in your hands™

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Trabecular Metal
Acetabular Revision System Cage
Data Sheet portion

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Acetabular Cage Surgical Technique

EXPOSURE AND ACETABULAR ASSESSMENT

Expose the acetabulum. Carefully assess any acetabular bone defects, noting the location, extent, and defect type. Also assess the quality and location of the host bone that remains for support of the acetabular reconstruction.

Determine which *Trabecular Metal* components will be used to reconstruct the acetabulum. If a *Trabecular Metal* Restrictor is to be used, it should be placed before the other components.

STEP 1: PREPARE THE ACETABULUM

Use morselized bone and structural graft as needed to reconstruct the acetabulum. Use ball impactors and/or reverse reamers to impact the bone graft. Identify the hip center and use the acetabular reamers to size and shape the acetabulum for the *Trabecular Metal* Revision Shell. The diameter of the last reamer used to shape the acetabulum will match the labeled diameter of the *TM* Revision Shell.

STEP 2: IMPLANT THE REVISION SHELL

Impact the shell into the prepared acetabulum, ensuring that the cluster of holes is positioned posterosuperiorly. Use a depth gauge through the screw holes to assess the contact between the acetabular cup and the host bone. Then drill the screw holes and insert the screws. Bicortical screw fixation is not necessary. **Note:** Do not overtighten the screws.

With the *TM* Revision Shell and/or other *TM* components in place, assess the stability of the construct within the acetabulum. When additional stability is needed, the *TM* Acetabular System Cage can be used to provide immediate stability until biological ingrowth within the *Trabecular Metal* material provides long-term stability.

STEP 3: PREPARE ISCHIAL NOTCH FOR INFERIOR FLANGE

Palpate the posterior rim of the acetabulum from superior to inferior to identify the ischium. Drill a small hole and use a depth gauge to confirm that the ischium has been located. The depth gauge should indicate at least 2.5cm of bone. Drill additional holes to confirm the proper orientation, ensuring that the location is surrounded by adequate bone stock.

Hold a small osteotome in line with the ischium and initiate a slot in the bone to accept the inferior flange of the cage. **Note: Care should be taken to avoid the sciatic nerve.** Insert the inferior flange of the cage provisional into the slot and use the flange to complete preparation of the ischial notch.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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STEP 4: IMPLANT THE CAGE

Extend acetabular exposure so that adequate preparation of the ilium can be achieved to accept the superior flange of the cage. Then use plate benders to contour the flanges on the cage provisional to fit the patient's anatomy. Insert the inferior flange into the slot created in the ischium, and impact the dome of the cage provisional.

After confirming the desired shape and fit of the cage provisional, remove the provisional component and contour the final implant to match that of the provisional component. **Note: Avoid reverse bending of the titanium implant as this may weaken or break the flange.** It is important to completely contour the implant before inserting screws so the cage will not be displaced when the screws are tightened.

Once the desired shape of the cage has been achieved, insert the inferior flange into the ischial notch and position the superior flange against the lateral portion of the ilium. Then impact the dome of the cage. It is not necessary for the cage to bottom out in the shell.

For additional stabilization, one or two screws may be inserted through the existing holes in the dome and into the corresponding holes in the *Trabecular Metal* Shell if hole alignment is achieved during insertion. If possible, insert one of these screws into the posterior column. Once the shell is stable, insert two or three screws through the existing holes in the superior flange of the cage.

STEP 6: INSERT THE ACETABULAR LINER

Apply doughy bone cement into the dome of the cage. Then insert the acetabular liner into the desired position within the dome, and impact it. The cement will pass through the holes in the cage to fill gaps between the cage and the acetabular shell.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Zimmer Research Report

(b)(4) Testing

[redacted]

(b)(6)

[redacted] /06

Sr. Engineer I
Structural Design & Analysis

Associate Director
Hip Development

Sr. Engineer II
Hip Development

(b)(6)

[redacted] 04/25/2006

Specialist
Regulatory Affairs

Director
Analytical and Experimental Mechanics

KEYWORDS: (b)(4) [redacted]

CONFIDENTIAL
This document contains proprietary and confidential information owned by Zimmer, Inc. and should not be distributed without taking appropriate action to protect its contents according to Zimmer procedures.

(b)(4) [redacted]

Report Number: (b)(4) [redacted] (b)(4)

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CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

510(k) Notification-Traditional
Zimmer Trabecular Metal Acetabular
Revision System Cage
May 2, 2006

Livelink/Regulatory Affairs/Submission Master/(b)(4) 2006-05-02 12:43 p.m.

zimmer
P.O. Box 708
Warsaw, IN 46581-0708

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 103

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Ronald P. Jean

Subject: 510(k) Number K061226 / S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) no

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: LPH/II 888.3358

Additional Product Code(s) with panel (optional):

Review: Elizabeth [signature] (Branch Chief) OJDB (Branch Code) 8/2/06 (Date)

Final Review: [signature] (Division Director) 8/2/06 (Date)

Revised:4/2/03

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

TRADITIONAL 510(K) MEMORANDUM

TO: K061226/S001

FROM: Ronald P. Jean, Ph.D. 08/01/2006
General Engineer, FDA/CDRH/ODE/DGRND/OJDB

DATE: 08/01/2006

SUBJECT: Zimmer Trabecular Metal Acetabular Revision System Cage
Product/Panel Code: LPH/87 Class: II Classification: 888.3358

RECOMMENDATION SUMMARY:

I received Supplement 001 of Traditional 510(k) K061226 on 07/28/2006. The original 510(k) submission was given as a reassignment. The subject device is a titanium acetabular cage that is intended to be cemented in between Trabecular Metal Revision acetabular liners and shells. The Indications for Use Statement is similar to the cleared predicate device. In Supplement 001, the sponsor has provided [(b)(4)] [redacted] (b)(4) [redacted] (4) [redacted], and (b)(4) [redacted]. In terms of indications, design, materials, and anticipated performance, the subject device is similar to the predicate cage. Therefore, I recommend that the Zimmer Trabecular Metal Acetabular Revision System Cage be found substantially equivalent (SE) to the other legally marketed predicate devices.

I. COMPANY IDENTIFICATION:

Proprietary Name:	Trabecular Metal Acetabular Revision System Cage
Applicant/Sponsor:	Zimmer, Inc.
Address:	P.O. Box 708 Warsaw, Indiana 46581-0708
Contact Person:	Ms. Patricia Jenks Specialist, Corporate Regulatory Affairs
Phone Number:	(574) 371-8354
Fax Number:	(574) 372-4605
Registration Number:	1822565

II. PREDICATE DEVICE(S):

K960678 Burch/Schneider Reinforcement Cage Zimmer*
Formerly Centerpulse Orthopedics Ltd.

III. INTENDED USE/INDICATIONS:

This device is intended for cemented use only as part of a layered construct and is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

The indications listed are identical to those listed for K960678.

IV. DEVICE DESCRIPTION & MATERIALS:

This 510(k) is for the Zimmer Trabecular Metal Acetabular Revision System Cage. The subject device is intended to bridge the areas of acetabular bone loss in patients with acetabular bone deficiencies (e.g., pelvic defects and discontinuities). The cage is made from commercially pure titanium conforming to ISO 5832-2, identical to the predicate device; hence, biocompatibility should be comparable. The geometry of the cage is a metallic, dome-shaped flanged acetabular component with multiple screw holes for adjunct intraoperative peripheral stabilization of revision shell constructs. The subject device is intended to be layered between Zimmer Trabecular Metal Acetabular Revision Shells (K003181, K050937) and polyethylene acetabular liners (K051516) using bone cement. *The* [redacted] (b)(4) [redacted] (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

(b)(4) [redacted] The cage is available in 5 sizes in both left and right configurations. A superior short or long flange employing 5 or 10 screw holes, respectively, as options. A component list is provided on page 0025. Engineering drawings are provided on pages 0023-0024.

V. DEFICIENCY RESPONSES:

(b)(4)

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 061226/S001

Reviewer: Ronald P. Jean

Division/Branch: DGRND/OJDB

Device Name: Trabecular Metal Acetabular Revision System Cage

Product To Which Compared (510(K) Number If Known): K960678

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?		✓	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	✓		If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		✓	If YES = Stop NE
9. Accepted Scientific Methods Exist?	✓		If NO = Stop NE
10. Performance Data Available?	✓		If NO = Request Data
11. Data Demonstrate Equivalence?	✓		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

1. Intended Use: revision hip arthroplasty

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? N Is the device sterile? Y Is the device for single use? Y Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? N Is this device a kit? N Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

See memo

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?	n/a	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	n/a	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	n/a	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	n/a	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Ronald P. Jean

Subject: 510(k) Number K061226

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept). AI
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) no

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☑ Continued Confidentiality exceeding 90 day

Predicate Product Code with class: JDI/II 888.3350

Additional Product Code(s) with panel (optional):

Review: (Branch Chief) OJDB (Branch Code) 6-13-06 (Date)

Final Review: (Division Director) (Date)

Revised:4/2/03

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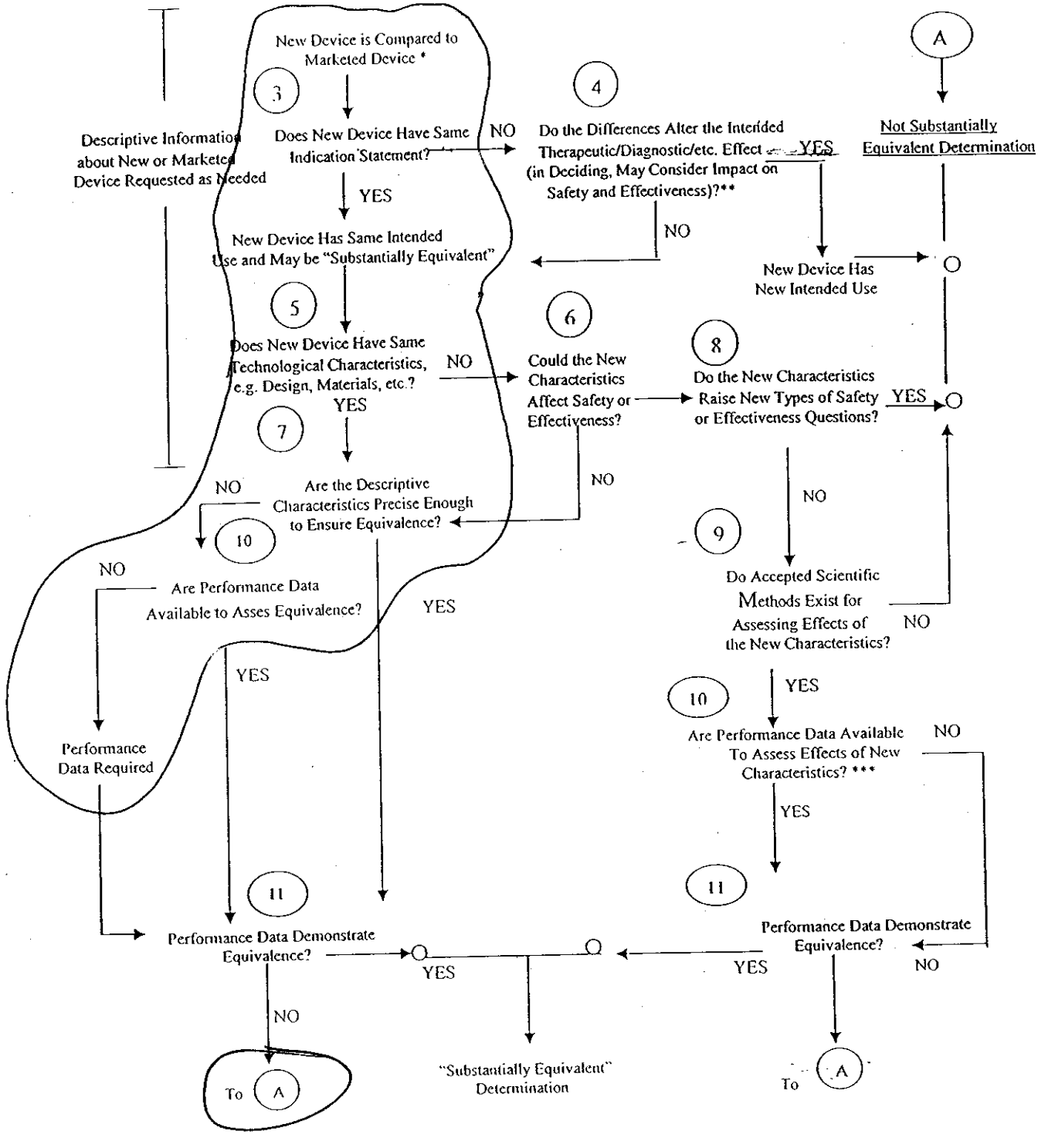
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-2517; Released by CDRH on 09-12-2016

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

TRADITIONAL 510(K) MEMORANDUM

TO: K061226

FROM: Ronald P. Jean, Ph.D. 06/13/2006 HM
General Engineer, FDA/CDRH/ODE/DGRND/OJDB

DATE: 06/13/2006

SUBJECT: Zimmer Trabecular Metal Acetabular Revision System Cage
Product/Panel Code: LPH/87 Class: II Classification: 888.3358

RECOMMENDATION SUMMARY:

I received Traditional 510(k) K061226 on 06/02/2006 as a reassignment. The current 510(k) submission is for a titanium acetabular cage. The Indications for Use Statement is similar to the cleared predicate device, although the sponsor will be asked to [redacted] (This device is intended to interface between the acetabular shell and liner; the sponsor will need to [redacted] (In addition, the sponsor will be asked (b)(4) [redacted] Lastly, the sponsor will be asked to (b)(4) [redacted]. Please see the section "V. Deficiencies" for additional information. Therefore, I recommend that this submission be placed on **hold** for additional information (**AI**) before a final SE/NSE decision can be made.

I. COMPANY IDENTIFICATION:

Proprietary Name:	Trabecular Metal Acetabular Revision System Cage
Applicant/Sponsor:	Zimmer, Inc.
Address:	P.O. Box 708 Warsaw, Indiana 46581-0708
Contact Person:	Ms. Patricia Jenks Specialist, Corporate Regulatory Affairs
Phone Number:	(574) 371-8354
Fax Number:	(574) 372-4605
Registration Number:	1822565

II. PREDICATE DEVICE(S):

K960678 Burch/Schneider Reinforcement Cage Zimmer*
Formerly Centerpulse Orthopedics Ltd.

III. INTENDED USE/INDICATIONS:

This device is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

The indications listed are identical to those listed for K960678. However, the subject device (b)(4) [redacted] (b)(4) [redacted]

IV. DEVICE DESCRIPTION & MATERIALS:

This 510(k) is for the Zimmer Trabecular Metal Acetabular Revision System Cage. The subject device is intended to bridge the areas of acetabular bone loss in patients with acetabular bone deficiencies (e.g., pelvic defects and discontinuities). The cage is made from commercially pure titanium conforming to ISO 5832-2, identical to the predicate device; hence, biocompatibility should be comparable. The geometry of the cage is a metallic, dome-shaped flanged acetabular component with multiple screw holes for adjunct intraoperative peripheral stabilization of revision shell constructs. The subject device is intended to be layered between Zimmer Trabecular Metal Acetabular Revision Shells (K003181, K050937) and polyethylene acetabular liners (K051516) using bone cement (b)(4) [redacted] (b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

(b)(4) [redacted] The cage is available in 5 sizes in both left and right configurations. A superior short or long flange employing 5 or 10 screw holes, respectively, as options. A component list is provided on page 0025. Engineering drawings are provided on pages 0023-0024.

V. DEFICIENCIES:

(b)(4) [redacted]

VI. STERILITY AND PACKAGING:

The sponsor provided the following sterilization information on page 0013:

Method of Sterilization:	Gamma Radiation
Min./Max. Dosage:	25/40 kGy
Method of Validation:	VDmax per AAMI TIR-27:2001
Sterility Assurance Level:	not specified
Single-Use Only:	Yes
Provided Sterile:	Yes
Description of Packaging:	The product is placed into a nylon/polyethylene pouch which is heat sealed with a peelable seal. This sealed pouch is then placed into another nylon/polyethylene pouch and heat sealed creating a double barrier. Sterile package protection is afforded by a third, protective pouch, also a nylon/polyethylene pouch and a solid bleach sulfate folding carton and shrink film.
Pyrogen Statement:	No claims regarding pyrogenicity are made.

The sponsor will be asked to (b)(4) [redacted]

VII. LABELING:

The sponsor provided draft labels on page 0030. The device name, reference number, lot number, material, expiration date, and method of sterilization are all present. *The contents are adequate.*

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

VIII. PACKAGE INSERT:
The sponsor provided a draft package insert on pages 0026-0029. A general statements section, device description, indications, information for use, contraindications, warnings, precautions, adverse events, and sterility information are all present. (b)(4) [redacted]

IX. 510K SUMMARY:
The sponsor provided a 510(k) Summary on page 0016. The sponsor contact information, device name, classification, regulation number, device description, and intended use sections are all present. *The sponsor will be asked* (b)(4) [redacted]

X. PERFORMANCE DATA:
(b)(4) [redacted]
(b)(4) [redacted]

XI. SE DETERMINATION:
At this time, additional information (**AI**) is necessary before an SE/NSE determination can be made.

XII. CONTACT RECORD:
None.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?	n/a	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	n/a	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	n/a	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	n/a	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517 (54) Released by CDRH on 09-12-2016

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K061226

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☑ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	n/a	
Class III Certification and Summary. **	n/a	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	n/a	
510(k) Kit Certification ***	n/a	

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		

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For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓ same as predicate matl	
b) Sterilization and expiration dating information:		
i) sterilization process	✓	
ii) validation method of sterilization process	✓	
iii) SAL		✓
iv) packaging	✓	
v) specify pyrogen free	✓	
vi) ETO residues	n/a	
vii) radiation dose	✓	
viii) Traditional Method or Non-Traditional Method	✓	
c) Software Documentation:	n/a	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No

Reviewer: Ronald P. Jean

Concurrence by Review Branch: [signature]

Date: 06/13/2006

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 061226

Reviewer: Ronald P. Jean

Division/Branch: DGRND/OJDB

Device Name: Zimmer Trabecular Metal Acetabular ~~Augment~~ Revision System Cage

Product To Which Compared (510(K) Number If Known): K960678

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?		✓	If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

See Memo

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Intended Use: acetabular cage for hip arthroplasty bone defects

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device ~~life-supporting~~ or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? N Is the device sterile? Y Is the device for single use? Y Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? N Is this device a kit? N Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

See memo

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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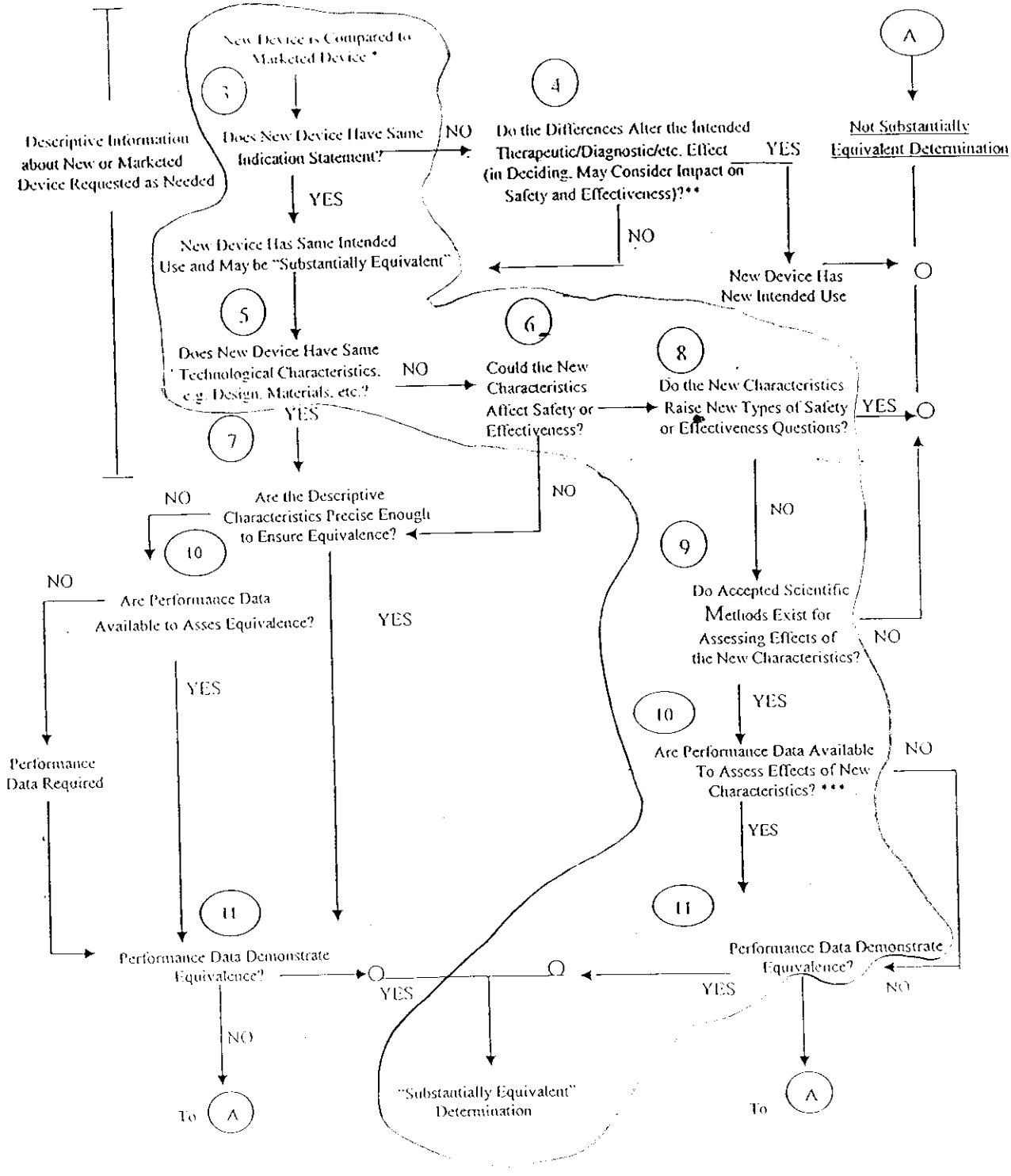
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 27, 2006

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: PATRICIA JENKS

510(k) Number: K061226
Product: TRABECULAR METAL ACETABULAR REVISION SYSTEM CAGE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

CDRH Submission Cover Sheet

Date of Submission:	FDA Document Number:
July 26, 2006	K061226

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☒ Original submission: ☒ Traditional ☐ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):
IDE	**Humanitarian Device Exemption**	**Class II Exemption**	**Evaluation of Automatic Class III Designation**	**Other Submission**
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B — Applicant or Sponsor

Company/Institution name: Zimmer, Inc.	Establishment registration number: 1822565
Division name (if applicable): N/A	Phone number (include area code): 574-372-4485
Street address: P.O. Box 708	FAX number (include area code): 574-372-4605

City:	State/Province:	Country:	ZIP/Postal Code:
Warsaw	Indiana	USA	46581-0708

Contact Name: Toni Kingsley, Ph.D., RAC	
Contact Title: Vice President, Corporate Regulatory Affairs and Compliance	Contact e-mail address: toni.kingsley@zimmer.com

Section C — Submission Correspondent (If Different from Above)

Company/Institution name: Zimmer, Inc.	Establishment registration number: 1822565
Division name (if applicable): N/A	Phone number (include area code): 574-371-8354
Street address: P.O. Box 708	FAX number (include area code): 574-372-4605

City:	State/Province:	Country:	ZIP/Postal Code:
Warsaw	Indiana	USA	46581-0708

Contact Name: Patricia Jenks	
Contact Title: Specialist, Corporate Regulatory Affairs	Contact e-mail address: trish.jenks@zimmer.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section D1 — Reason for Submission -- PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Change in design, component or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Reponse to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):

Section D2 — Reason for Submission -- IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ Other reason (specify):

Section D3 — Reason for Submission – 510(k)

- ☒ New device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):
- ☐ Change in technology
- ☐ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 LPH	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K960678	1 *Burch/Schneider*™ Reinforcement Cage	1 Zimmer GmbH-(formerly Centerpulse Orthopedics Ltd.)
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F Product Information – Applicable to All Applications

Common or usual name or classification name: Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous, Uncemented

Trade or proprietary or model name	Model number
1 *Trabecular Metal*™ Acetabular Revision System Cage	1 See Exhibit G
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 K003181	2 K050937	3 K051516	4	5	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☐ Human trials

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section G — Product Classification – Applicable to All Applications

Product code:	C.F.R. Section	Device class:
LPH	888.3358	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Orthopedics/87		

Indications (from labeling):

This device is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H — Manufacturing/Packaging/Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA Establishment registration number: (b)(4) [redacted]	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract manufacturer ☐ Repackager/Relabeler

(b)(4) [redacted]

☒ Original ☐ Add ☐ Delete	FDA Establishment registration number: (b)(4) [redacted]	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract manufacturer ☐ Repackager/relabeler

Company/Institution name:

(b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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zimmer

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

K061226/S1

July 26, 2006

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food & Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Dear Sir or Madam:

Subject: *Zimmer® Trabecular Metal™* Acetabular Revision System Cage-K061226

The following is being submitted in response to FDA's letter received June 23, 2006, requesting additional information. For convenience and clarity, the agency's questions are presented followed by our response.

(b)(4) Deficiencies

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Deficiencies

[redacted]

All data and information submitted herein are truthful and accurate to the best of my knowledge and no material fact has been omitted. If you require any additional information or have any questions, please contact me by telephone at (574) 371-8354, by fax at (574) 372-4605 or by e-mail at trish.jenks@zimmer.com.

Sincerely,

Patricia Jenks
Specialist, Corporate Regulatory Affairs

pj/me
RA066502K.LT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Zimmer Research Report

(b)(4) Testing [redacted]

(b)(6) [redacted] 7-17-06

Principal Engineer
Fatigue and Fracture Mechanics

Senior Development Engineer II
Hips GBMC

(b)(6) [redacted] 7/19/06

Sr Research Engineer
Biomechanics Test Lab

Director
Experimental and Analytical Research

(b)(6) [redacted] 7/18/06

Regulatory Affairs Specialist

KEYWORDS: (b)(4) Testing [redacted]

CONFIDENTIAL
This document contains proprietary and confidential information owned by Zimmer, Inc. and should not be distributed without taking appropriate action to protect its [illegible]

(b)(4) [redacted] (b)(4) Testing [redacted]

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Confidential and Proprietary Information Exempt from Disclosure under FOI
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Patricia Jenks Specialist, Corporate Regulatory Affairs Telephone: (574) 371-8354 Fax: (574) 372-4605
Date:	July 26, 2006
Trade Name:	Zimmer *Trabecular Metal*™ Acetabular Revision System Cage
Common Name:	Acetabular Cage
Classification Name and Reference:	Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous, Uncemented 21 CFR § 888.3358
Predicate Device:	*Burch/Schneider*™ Reinforcement Cage, K960678, cleared May 3, 1996, manufactured by Zimmer GmbH (formerly Centerpulse Orthopedics Ltd.)
Device Description:	The Zimmer *Trabecular Metal* Acetabular Revision System Cage is a device intended to bridge the areas of acetabular bone loss in patients with acetabular bone deficiencies, such as pelvic defects and discontinuities. The cage is a metallic, dome-shaped, flanged acetabular component with multiple screw holes for adjunct intraoperative peripheral stabilization of revision shell constructs. The cage is available in five sizes configured in both right and left versions along with either short or long flanges to meet various anatomical needs. It offers intraoperative flexibility of implant orientation/positioning to accommodate patient anatomies. The cage is fabricated from Commercially Pure (CP) Titanium.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Intended Use:	This device is intended for cemented use only as part of a layered construct and is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.
Comparison to Predicate Device:	Both the predicate and proposed devices are intended for revision hip surgeries to bridge the areas of acetabular bone loss in patients with acetabular bone deficiency.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Engineering evaluations were performed to verify that the performance of the device would be adequate for anticipated in vivo use. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1517; Released by CDRH on 09-12-2016

Indications for Use

510(k) Number (if known):

Device Name:

Zimmer *Trabecular Metal*™ Acetabular Revision System Cage

Indications for Use:

This device is intended for cemented use only as part of a layered construct and is indicated for patients with conditions of, but not limited to, acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery, advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis, and failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118