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
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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.

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.

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

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

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