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Summary of Safety and Effectiveness

MAY 12 2006

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Karen Cain, RAC Manager, Corporate Regulatory Affairs Telephone: (574) 372-4219 Fax: (574) 372-4605
Date:	January 5, 2006
Trade Name:	*Zimmer*® M/L Taper Hip Prosthesis
Common Name:	Total Hip Prosthesis
Classification Names and References:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR § 888.3358, product code LPH Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR § 888.3353, product codes MEH, LZO
Predicate Devices:	*Zimmer*® M/L Taper Hip Prosthesis, K032726, cleared October 22, 2003 *Zimmer* M/L Taper Hip Prosthesis with *Calcicoat*® Ceramic Coating, K042337, cleared November 4, 2004 *Zimmer CPT*® 12/14, K030265, cleared March 4, 2003 *Zimmer VerSys*® Beaded Mid-Coat Stem, K973714, cleared December 24, 1997
Device Description:	The *Zimmer* M/L Taper Hip Prostheses are flat, collarless, modular femoral stems with a proximal to distal taper in the mediolateral plane. The

prostheses are circumferentially coated with titanium alloy plasma spray over the proximal body region and are available in standard and extended offset options, with or without *Calcicoat* Ceramic Coating.

Intended Use:

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

Hemi-hip replacement for the following: fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

Comparison to Predicate Device:

An additional size option and an additional neck length option are being added to the previously cleared *Zimmer* M/L Taper Hip Prosthesis system.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Analysis of the modified devices indicates that they are substantially equivalent to the predicates.

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

MAY 12 2006

Zimmer, Inc.
c/o Ms. Karen Cain
Manager, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K060040
Trade/Device Name: *Zimmer*® M/L Taper Hip Prosthesis
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, MEH, LZO
Dated: April 13, 2006
Received: April 14, 2006

Dear Ms. Cain:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K060040

Indications for Use

510(k) Number (if known):

Device Name:

Zimmer® M/L Taper Hip Prosthesis

Indications for Use:

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

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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)

[signature]

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

(510(k) Number K060040