K063251

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Summary of Safety and Effectiveness

JAN 24 2007

Submitter:

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

Contact Person:

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Senior Associate, Regulatory Affairs
Telephone: (574) 372-4907
Fax: (574) 372-4605

Date:

January 23, 2006

Trade Name:

Zimmer® M/L Taper Hip Prosthesis with Modular Neck Technology

Common Name:

Total Hip Prosthesis

Classification Name and Reference:

1. KWA - Hip joint metal/metal semi-constrained with uncemented acetabular shell, 21 CFR § 888. 3330

2. JDL - Hip joint metal/metal semi-constrained with cemented acetabular shell, 21 CFR § 888. 3320

3. LPH - Prosthesis, hip, semi-constrained metal/polymer porous uncemented, 21 CFR § 888. 3358

4. LWJ - Prosthesis, hip, semi-constrained metal/polymer uncemented (hemi-hip), 21 CFR § 888. 3360

5. MEH - Prosthesis, hip, semi-constrained uncemented metal polymer, non-porous, calcium phosphate, 21 CFR § 888. 3353

Predicate Device:

Zimmer® M/L Taper Hip Prosthesis, manufactured by Zimmer, Inc., K032726, cleared October 22, 2003

	Profemur TL Hip Stem manufactured by Wright Medical Technology, Inc., K060358, cleared May 10, 2006 *Zimmer*® M/L Taper Hip Prosthesis with *Calcicoat*® Ceramic Coating, manufactured by Zimmer, Inc., K042337, cleared November 4, 2004
Device Description:	The *Zimmer* M/L Taper Hip Prosthesis with Modular Neck Technology is a modular, wedge-shaped stem that is coated with commercially pure titanium alloy plasma spray that is available with and without *Calcicoat* Ceramic Coating. This stem is designed for cementless use only. The modular neck option allows for soft tissue balancing and easier restoration of the hip joint center of rotation. The modularity feature will allow surgeons to independently equalize leg length and optimize offset while, at the same time, maximizing joint stability for a variety of different patients' anatomies.
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. This femoral stem is for cementless use only.

Comparison to Predicate Device:	The M/L Taper Hip Prosthesis with Modular Neck Technology is packaged, manufactured, and sterilized using the same materials and processes as the predicate devices. The subject device also has the same intended use and fixation methods as the predicate devices.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-clinical testing demonstrated that the M/L Taper Hip Prosthesis with Modular Neck Technology met performance requirements and is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zimmer, Inc.
c/o Ms. Dalene T. Binkley
Senior Associate, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

JAN 24 2007

Re: K063251
Trade/Device Name: Zimmer® M/L Taper Hip Prosthesis with Modular Neck Technology
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LPH, LWJ, MEH, LZO
Dated: October 26, 2006
Received: October 27, 2006

Dear Ms. Binkley:

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.

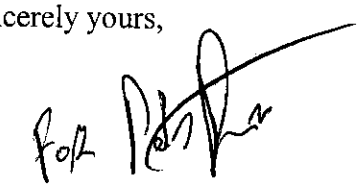
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Enclosure

K063251

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Indications for Use

510(k) Number (if known):

Device Name:

Zimmer® M/L Taper Hip Prosthesis with Modular Neck Technology

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.

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.

This femoral stem is for cementless use only.

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 K063251