K032726

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Laura D. Williams, RAC Sr. Associate, Regulatory Affairs Telephone: (574) 372-4523 Fax: (574) 372-4605
Date:	August 28, 2003
Trade Name:	*Zimmer*® M/L Taper Hip Prosthesis
Common Name:	Total Hip Prosthesis
Classification Name	Hip joint metal/polymer/metal semiconstrained porous coated uncemented prosthesis
Reference and Product Code:	21 CFR § 888.3358, LPH
Predicate Device:	1. Biomet Taperloc, K921301, cleared 2-16-94; and K020963, cleared 4-16-02 2. Zimmer *ZMR*® Hip System Porous Revision, K994286, cleared 3-10-00 3. Zimmer *VerSys*® Hip System Fiber Metal Taper Hip Prosthesis, K964769, cleared 3-13-97
Device Description:	The *Zimmer*® M/L Taper Hip Prosthesis is a modular, titanium alloy femoral stem designed to replace the proximal human femur in total hip arthroplasty. It is flat, collarless, and features a proximal-to-distal taper in the mediolateral (M/L) plane. The wedge-shaped prosthesis is designed for cementless use and is circumferentially porous-coated with titanium alloy plasma spray over the proximal body region.
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:

The M/L Taper Hip Prosthesis 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 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

OCT 2 2 2003

Ms. Laura D. Williams, RAC
Sr. Associate, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Re: K032726
Trade/Device Name: Zimmer® M/L Taper Hip Prosthesis, 7711 Series
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: September 2, 2003
Received: September 3, 2003

Dear Ms. Williams:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
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): K032726

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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for Mark N Milhous

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

510(k) Number K032726

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)