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Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Dalene T. Binkley Associate, Regulatory Affairs Telephone: (574) 372-4907 Fax: (574) 372-4605
Date:	April 27, 2004
Trade Name:	*Zimmer*® Anatomic II Hip Prosthesis
Common Name:	Prosthesis, Hip, Semi-constrained, Metal/Polymer, Porous, Uncemented
Classification Name and Reference:	LPH 21 CFR § 888.3358
Predicate Device:	*Zimmer* Anatomic Hip Prosthesis, manufactured by Zimmer, K922071, cleared February 22, 1994.
Device Description:	The *Zimmer* Anatomic II Hip Prosthesis is an anatomically shaped femoral stem for use in total hip arthroplasty. It is manufactured from *Tivanium*® Ti-6Al-4V Alloy and utilizes a modular junction between the head and neck. Biological fixation is achieved with the use of a *Tivanium* Ti-6Al-4V plasma spray coating. The modular connection of the femoral stem is a Morse-type 12/14 taper designed to mate with the corresponding femoral head component. *Zimaloy*® Co-Cr-Mo Alloy femoral heads are available for use with the femoral stem or, where available, Alumina Ceramic Femoral Heads. The modified *Zimmer* Anatomic Stems have been developed to increase surgeons' options so that they may meet the large variety of anatomical needs of their patients.

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Intended Use:

The *Zimmer* Anatomic II Hip Prosthesis is indicated for:
- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis.
- Patients suffering from disability due to previous fusion.
- Patients with acute femoral neck fractures.

Comparison to Predicate Device:

The modifications to the *Zimmer* Anatomic Hip Prosthesis change neither the intended use nor the fundamental scientific technology of the device. It is packaged and sterilized using the same materials and processes.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-clinical performance testing demonstrated that the modified device is equivalent to the predicate.

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

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

JUL 2 0 2004

Re: K041109
Trade Name: *Zimmer*® Anatomic II Hip Prosthesis
Regulation Numbers: 21 CFR 888.3358
Regulation Names: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Codes: LPH
Dated: June 25, 2004
Received: June 28, 2004

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 (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

K041109

Indications for Use

510(k) Number (if known):

Device Name:

Zimmer® Anatomic II Hip Prosthesis

Indications for Use:

The *Zimmer* Anatomic II Hip Prosthesis is indicated for:
- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis.
- Patients suffering from disability due to previous fusion.
- Patients with acute femoral neck fractures.

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

for Mark N Milhern

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

510(K) Number K041109