

K042337

NOV - 4 2004

Summary of Safety and Effectiveness

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

Contact Person: Dalene Binkley, RAC
Associate, Regulatory Affairs
Telephone: (574) 372-4907
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Date: August 27, 2004

Trade Name: *Zimmer*[®] M/L Taper Hip Prosthesis with *Calcicoat*[®]
Ceramic Coating

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

Device Description: The *Zimmer*[®] M/L Taper Hip Prosthesis with
Calcicoat[®] Ceramic Coating 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.
Calcicoat[®] Ceramic Coating (hydroxyapatite
tricalcium phosphate [HA/TCP]) has been added to
the porous coating to aid bony ingrowth.

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 with *Calcicoat*[®] Ceramic Coating is manufactured, packaged, 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 *Calcicoat*[®] Ceramic Coating met performance requirements and is as safe and effective as the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2004

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

Re: K042337

Trade/Device Name: Zimmer® M/L Taper Hip Prosthesis with Calicoat® Ceramic Coating

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: October 13, 2004

Received: October 15, 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.

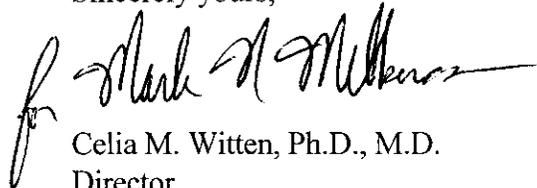
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Ms. Darlene Binkley, RAC

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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right.

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):

Device Name:

Zimmer® M/L Taper Hip Prosthesis with *Calcicoat** Ceramic Coating

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)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K042337 Page 1 of 1