

Summary of Safety and Effectiveness

JUN 30 2005

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

Contact Person: Dalene T. Binkley, RAC
Senior Associate, Regulatory Affairs
Telephone: (574) 372-4907
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Date: June 24, 2005

Trade Name: *Trabecular Metal*TM Primary Hip Prosthesis

Common Name: Total Hip Prosthesis

Classification Name and Reference: LPH
21 CFR § 888.3358

Predicate Device: *VerSys*TM Hip System – Fiber Metal Taper Hip Prosthesis, manufactured by Zimmer, Inc., K964769, cleared February 13, 1997

Device Description: The *Trabecular Metal* Primary Hip Prosthesis is intended to be a single use only implant that is used to replace a hip joint.

The wedge-shaped prosthesis is designed for cementless use and is circumferentially bonded with *Trabecular Metal* over the proximal body region for biological fixation. The hip is offered in a broad range of sizes designed to accommodate varying patient anatomy with standard and extended neck offsets.

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 *Trabecular Metal* Primary Hip Prosthesis is packaged, manufactured, and sterilized using the same materials and processes as the predicate device. The subject device also has the same intended use and fixation methods as the predicate device.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-clinical testing demonstrated that the *Trabecular Metal* Primary Hip Prosthesis is as safe and effective as its predicate device.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.



JUN 30 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K051491
Trade/Device Name: *Trabecular Metal*TM Primary Hip Prosthesis
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: June 03, 2005
Received: June 06, 2005

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.

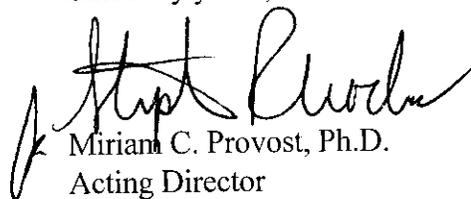
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam C. Provost". The signature is fluid and cursive, with a large initial "M" and "P".

Miriam C. Provost, Ph.D.
Acting 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): K051491

Device Name:

*Trabecular Metal*TM Primary 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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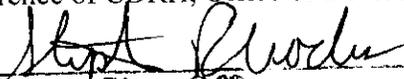
Prescription Use X
(Part 21 CFR 801 Subpart D)

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)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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510(k) Number K051491