NOV - 5 2003

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Karen Cain Manager, Regulatory Affairs Telephone: (574) 372-4219 Fax: (574) 372-4605
Date:	September 22, 2003
Trade Name:	*VerSys*® Beaded FullCoat Calcar Hip Prosthesis
Common Name:	Hip prosthesis
Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR § 888.3358
Predicate Device:	*VerSys* Beaded FullCoat Bowed Revision Hip Prosthesis, manufactured by Zimmer, K030079, cleared February 5, 2003
Device Description:	Like its predicate, the *VerSys* Beaded FullCoat Calcar Hip Prosthesis is a modular femoral stem manufactured from Co-Cr-Mo alloy and has a sintered Co-Cr-Mo alloy bead porous surface coating. The modified device features a calcar region designed with 10 and 20mm build-up heights in both straight and bowed hip stems.
Intended Use:	The *VerSys* Beaded FullCoat Calcar Hip Prosthesis is designed to achieve biologic fixation to bone and is indicated for: 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 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 modifications to the *VerSys* Beaded FullCoat Bowed Revision Hip Prosthesis do not change either the intended use or the fundamental scientific technology of the device. It is packaged and sterilized utilizing the same materials and processes. The modified device is designed to offer another revision style line extension to the existing system of implants.

Performance Data:

Finite element analysis demonstrated that the device is equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

Ms. Karen Cain
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K033034
Trade/Device Name: *Versys* ® Beaded FullCoat Calcar 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: September 26, 2003
Received: October 6, 2003

Dear Ms. Cain:

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): K033034

Device Name:

VerSys® Beaded FullCoat Calcar Hip Prosthesis

Indications for Use:

The *VerSys* Beaded FullCoat Calcar Hip Prosthesis is designed to achieve biologic fixation to bone and is indicated for:

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 fractures, secondary avascular necrosis of the femoral head, pathological fractures of the femoral neck, and osteoarthritis in which the femoral head is primarily affected.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K033034

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