K061786

Summary of Safety and Effectiveness

7/24/06

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Patricia Jenks Specialist, Regulatory Affairs Telephone: (574) 371-8354 Fax: (574) 372-4605
Date:	June 23, 2006
Trade Name:	*VerSys*® Fiber Metal MidCoat Low Head Center Hip Prosthesis
Common Name:	Total Hip Prosthesis
Classification Name and Reference:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer Porous, Uncemented 21 CFR § 888.3358
Predicate Device:	*VerSys* Beaded MidCoat Low Head Center Hip Prosthesis, manufactured by Zimmer, K042776, cleared November 4, 2004
Device Description:	Like its predicate, the *VerSys* Fiber Metal MidCoat Low Head Center Hip Prosthesis is a cementless, straight, modular femoral stem. The proposed and predicate devices are designed with trapezoidal geometry and feature 12/14 Morse-type proximal neck tapers to mate with the corresponding 12/14 bore of a femoral head component. Both devices feature 125-degree neck angles and distal, longitudinal splines. The modified device is manufactured from *Tivanium*® Alloy and has circumferential, commercially-pure titanium fiber

	metal pads for biological fixation.
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 modifications to the *VerSys* Fiber Metal MidCoat Low Head Center Hip Prosthesis change neither the intended use nor the fundamental scientific technology of the device as compared to the predicate. The modified and unmodified device use the same materials and processes for packaging and sterilization.
Performance Data (Nonclinical and/or Clinical):	Non-clinical performance testing 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

Zimmer, Inc.
c/o Patricia Jenks
Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

JUL 24 2006

Re: K061786
Trade/Device Name: *VerSys*® Fiber Metal MidCoat Low Head Center Hip Prosthesis
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: June 23, 2006
Received: June 26, 2006

Dear Ms. Jenks:

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 (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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061786

Indications for Use

510(k) Number (if known):

Device Name:

VerSys® Fiber Metal MidCoat Low Head Center 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.

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.

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)

Patricia Cohen MD

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K061786