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Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Eric S. Pittman Associate, Corporate Regulatory Affairs Telephone: (574) 371-8369 Fax: (574) 372-4605
Date:	March 15, 2008
Trade Name:	*VerSys*® *Epoch*® FullCoat Hip System
Common Name:	Proximal Femoral Prosthesis
Classification Name and Reference:	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21 CFR § 888.3320-JDL)
Predicate Device:	*VerSys*® *Epoch*® FullCoat Hip System, manufactured by Zimmer, Inc., K052321, cleared February 15, 2006.
Device Description:	The *VerSys Epoch* FullCoat Hip stem is an addition to the currently marketed *VerSys Epoch* FullCoat proximal femoral hip implant family. It is a set of fully porous coated implants that are comprised of Zimaloy™, a cobalt chromium molybdenum (CoCrMo) alloy core surrounded by a layer of injection molded polyetheretherketone (PEEK) encased in a layer of commercially pure titanium fiber metal (FM). The stem is designed to replace the proximal femur in a total hip arthroplasty. It features a 12/14 Morse-type taper to accommodate the attachment of modular femoral heads. The proximal geometry of the device is trapezoidal and comes in two options Reduced Neck Length (RNL)

	with 125° and 135° angles and Low Head Center (LHC) with a 125° angle.
Intended Use:	The *VerSys Epoch* FullCoat 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. This device is intended for cementless use only.
Comparison to Predicate Device:	Compared to the predicate, the subject device has the same intended use, similar physical and performance characteristics and is manufactured using similar processes.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Mechanical testing of the device indicated that it is substantially equivalent to the legally market 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

NOV 18 2008

Zimmer, Inc.
% Ms. Natalie S. Heck
Sr. Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K073499
Trade/Device Name: *VerSys® Epoch®* FullCoat Hip System
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, JDL
Dated: July 28, 2008
Received: July 30, 2008

Dear Ms. Heck:

This letter corrects our substantially equivalent letter of August 7, 2008.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Mark N. Melkerson DLP 11/13/07

Mark N. Melkerson
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): K073499

Device Name:

VerSys® *Epoch*® FullCoat Hip System

Indications for Use:

The *VerSys Epoch* FullCoat 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.

This device is intended for cementless use only.

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 K073499