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Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Brandon Hipsher Associate, Corporate Regulatory Affairs Telephone: (574) 371-8083 Fax: (574) 372-4605
Date:	August 24, 2005
Trade Name:	*VerSys*® *Epoch*® Fullcoat Hip Prosthesis
Common Name:	Total Hip Prosthesis
Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR § 888.3358
Predicate Device:	*Epoch* Hip Prosthesis, manufactured by Zimmer, Inc., K014070, cleared July 30, 2002
Device Description:	The *VerSys Epoch* Fullcoat Hip Prosthesis is a modular, metal-polymer composite femoral stem designed to replace the proximal human femur in total hip arthroplasty. It features a 12/14 Morse-type taper to accommodate the attachment of modular femoral heads. The proximal body geometry of the proposed device is trapezoidal and two body options (standard and large metaphysis) are offered in sizes 13mm through 22mm to meet patient anatomical requirements. The *VerSys Epoch* Fullcoat Hip Prosthesis is available in both standard and extended neck offsets to allow for restoration of optimal joint kinematics and maximum stability without altering leg length.
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.

Comparison to Predicate Device:

The *VerSys Epoch* Fullcoat Hip Prosthesis is manufactured from similar materials to those used in the predicate device. It is packaged and sterilized using the same materials and processes as the predicate device.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-clinical testing demonstrated that this device met performance requirements and is as safe and effective as the predicate device.

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

FEB 15 2006

Mr. Brandon Hipsher
Associate, Corporate Regulatory Affairs,
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581

Re: K052321
Trade/Device Name: *VerSys® Epoch®* Fullcoat 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: January 26, 2006
Received: January 30, 2006

Dear Mr. Hipsher:

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) 594-4639. 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 may be obtained 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
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): K053321

Device Name:

VerSys® *Epoch*® Fullcoat Hip Prosthesis

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.

Prescription Use X AND/OR Over-The-Counter Use No
(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)

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

510(k) Number