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Summary of Safety and Effectiveness

- **Submitted By:**

  Zimmer, Inc.
  P.O. Box 708
  Warsaw, Indiana 46581-0708
  574-267-6131

- **Contact Person:**

  Karen Cain
  Manager, Regulatory Affairs
  Telephone: 574/372-4219
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- **Date:**

  July 22, 2002

- **Trade Name:**

  Epoch® Hip Prosthesis

- **Common Name:**

  Femoral Hip Prosthesis

- **Classification Name:**

  Prosthesis, hip, semi-constrained, composite/polymer

- **Predicate Devices:**

  - AML Total Hip System with Porocoat, manufactured by DePuy, P820024, approved for use without bone cement August 19, 1983 (formerly called the Porocoat Modified Austin-Moore Total Hip Prosthesis); Porocoat Porous Coating, K931641, cleared for use without bone cement March 21, 1994

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- *BIAS*® Total Hip System, manufactured by Zimmer, K842906, cleared for use with bone cement August 24, 1984; P850061, approved for use without bone cement January 31, 1989, subsequently downclassified to Class II on February 21, 1992

- *BIAS* Fiber Metal Total Hip Stem (TFB), manufactured by Zimmer, K934515, cleared August 24, 1995

- **Device Description**

The *Epoch* Hip Prosthesis is a femoral stem manufactured from cobalt-chromium-molybdenum alloy, polyaryletherketone (PAEK), and commercially pure (c.p.) titanium fiber metal pads. This design is intended to permit biological fixation over the entire length of the stem.

The femoral stem is anteverted proximally and is straight distally. The device is designed to fit the proximal femur and provide an interference fit with intimate contact between the porous titanium pads and the surrounding trabecular bone. The proximal one-third is wedge-shaped with a broad medial face for optimal stress distribution. The stem is available in left and right configurations in sizes ranging from 14 to 18 mm. The design includes progressive offsets that increase in proportion with stem size for optimal restoration of joint anatomy.

The head/neck junction features a Morse-type 12/14 taper designed to mate with the corresponding 12/14 bore of a variety of femoral head components.

- **Intended Use**

The *Epoch* Hip Prosthesis is indicated for:

1. 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.
2. Patients with congenital hip displasia, protrusio acetabuli, or slipped capital femoral epiphysis.
3. Patients suffering from disability due to previous fusion.
4. Patients with acute femoral neck fractures.

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- **Comparison to Predicate Devices**

  All hip systems listed above are substantially equivalent to each other and the *Epoch* Hip Prosthesis in that each is intended for cementless fixation into the intramedullary canal for pathological or generative conditions involving the femur and/or acetabulum.

- **Clinical Data**

  Clinical and radiographic performance of the *Epoch* Hip Prosthesis was evaluated in a six-year, multicenter clinical trial. All subjects were followed for two years and functional, radiographic and health-related quality of life evaluations were performed. Complication rates were low and comparable to literature reports for uncemented total hip arthroplasty. To date, no stems have been revised.

  Functional clinical assessment by the Harris Hip Analysis indicated "excellent" outcomes for the device. Thigh pain was reduced from 78.9% of patients preoperatively, to 4.3% at 24 months.

  DEXA analysis was completed on a subset of patients and suggests that periprosthetic bone loss attributable to stress shielding is less with the *Epoch* Hip Prosthesis than that observed in longitudinal studies of most other all-metallic femoral prostheses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2002

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

Re: K014070
Trade/Device Name: Epoch® Hip Prosthesis, Model 4075 Series
Regulatory 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: May 3, 2002
Received: May 7, 2002

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.

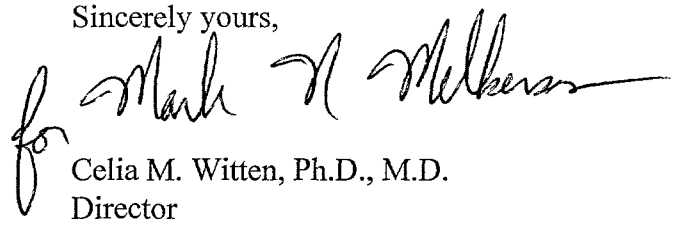
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, 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). 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit K

510(k) Number (if known K014070

Device Name: Epoch Hip Prosthesis

Indications for Use:

The *Epoch*® Hip Prosthesis is indicated for:

1. 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.
2. Patients with congenital hip displasia, protrusio acetabuli, or slipped capital femoral epiphysis.
3. Patients suffering from disability due to previous fusion.
4. Patients with acute femoral neck fractures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

RA03601K.510

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014070