zimmer

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DEC 24 1997

Summary of Safety and Effectiveness
***VerSys*® Hip System**
Beaded Hip Prosthesis

- **Submitted By:**

  Zimmer, Inc.
  P.O. Box 708
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  219-267-6131

- **Contact Person:**

  Karen Cain
  Specialist, Global Regulatory Affairs
  Telephone: 219/372-4219
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- **Date:**

  September 26, 1997

- **Trade Name:**

  VerSys® Hip System Beaded Hip Prosthesis

- **Common Name:**

  Femoral Hip Prosthesis

- **Classification Name:**

  Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

- **Predicate Devices:**

  - Beta System, manufactured by Zimmer, K953337, cleared January 22, 1996

  - AML Total Hip System with Porocoat, manufactured by DePuy, P820024, approved for use without bone cement August 19, 1993, (formerly called the Porocoat Modified Austin-Moore Total Hip Prosthesis); Porocoat Porous Coating, K931641, cleared for use without bone cement March 21, 1994

  - Prodigy Hip Prosthesis, manufactured by DePuy, K931641, cleared March 21, 1994

- **Device Description**

The *VerSys* Beaded Hip is a modular stem manufactured from *Zimaloy*® Cobalt-Chromium-Molybdenum Alloy and has a sintered Co-Cr-Mo alloy bead porous surface coating. The prosthesis features a 12/14 Morse-type taper to accommodate the attachment of modular Co-Cr-Mo alloy or zirconia ceramic femoral heads. Proximal body geometry of the *VerSys* Beaded Hip is trapezoidal and two body options (standard and large metaphysis) are offered in select sizes to meet patient anatomical requirements. The *VerSys* Beaded Hip Prosthesis is available in two porous coating length options, a midcoat option and a fullcoat option. The distal shaft of the midcoat stem has longitudinal splines. Flutes (grooves, channels) are featured on the distal anterior and posterior surfaces of the midcoat stem.

- **Indications for Use**

The *VerSys* Beaded 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 endoprotheses 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 Devices**

  - Beta System, manufactured by Zimmer, K953337, cleared January 22, 1996

  - AML Total Hip System with Porocoat, manufactured by DePuy, P820024, approved for use without bone cement August 19, 1993, (formerly called the Porocoat Modified Austin-Moore Total Hip Prosthesis); Porocoat Porous Coating, K931641, cleared for use without bone cement March 21, 1994

  - Prodigy Hip Prosthesis, manufactured by DePuy, K931641, cleared March 21, 1994

  All hip systems listed above are substantially equivalent to each other and the *VerSys* Hip System Beaded Hip in that each is intended for cementless fixation into the intramedullary canal for pathological or degenerative conditions involving the femur and/or acetabulum. All predicate devices are modular in design. Each has a Morse-type proximal neck taper to accommodate the attachment of a femoral head which, in turn, articulates upon the ultra-high molecular-weight polyethylene (UHMWPE) bearing surface of a total hip or hemi-hip acetabular component.

- **Clinical Data**

  One current method of femoral hip prothesis implantation relies upon mechanical fixation through initial implant stabilization with secondary fixation supplied by bone ingrowth. The *VerSys* Hip System Beaded Stem is an example of a device designed to achieve biologic fixation to bone without the use of bone cement. Many studies published in the literature report that satisfactory results have been obtained with the use of hip prostheses that are substantially equivalent to the *VerSys* Beaded Hip Prosthesis.

RA09702K.510

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 24 1997

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

Re: K973714
Trade Name: VERSYS® Hip System Beaded Hip Prosthesis
Regulatory Class: II
Product Codes: LPH and LZO
Dated: September 26, 1997
Received: September 29, 1997

Dear Ms. Cain:

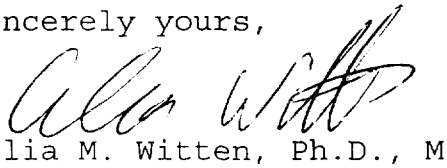
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/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 M

510(k) Number (if known): K973714

Device Name: *VerSys*® Hip System Beaded Hip Prosthesis

Indications for Use:

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- 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 endoprotheses 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.

(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 Devices
510(k) Number K973714

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

RA02650K.FM