K030079

Summary of Safety and Effectiveness

FEB 0 5 2003

Submitter:
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person:
Fred McClure, RAC
Sr. Associate, Regulatory Affairs
Telephone: (574) 372-4294
Fax: (574) 372-4605

Date:
January 8, 2003

Trade Name:
VerSys® Beaded Fullcoat Bowed Revision 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:
VerSys Hip System Beaded Hip Prosthesis, manufactured by Zimmer, K973714, cleared December 24, 1997

Device Description:
Like its predicate, the *VerSys* Beaded Fullcoat Bowed Revision Hip Prosthesis is a modular femoral stem manufactured from Co-Cr-Mo alloy and has a sintered Co-Cr-Mo alloy bead porous surface coating. The prosthesis features a 12/14 Morse-type proximal neck taper to mate with the corresponding 12/14 bore of a femoral head component. Proximal body geometry of the prosthesis is trapezoidal.

Intended 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,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Fred McClure, RAC
Sr. Associate, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K030079
Trade/Device Name: VerSys® Beaded Fullcoat Bowed Revision 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 8, 2003
Received: January 9, 2003

Dear Mr. McClure:

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). 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

Celia M. Witten, Ph.D., M.D.
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): K030079

Device Name:

VerSys® Beaded Fullcoat Bowed Revision Hip Prosthesis

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, protrusion 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 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)

for Mark N. Melkerson

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

510(k) Number K030079

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