MAR 10 2000

K994286

P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

Summary of Safety and Effectiveness

- **Submitted By:**

  Zimmer, Inc.
  P.O: Box 708
  Warsaw, Indiana 46581-0708
  219-267-6131

- **Contact Person:**

  Karen Cain
  Senior Regulatory Affairs Associate
  Telephone: 219/372-4219
  Fax: 219/372-4605

- **Date:**

  December 17, 1999

- **Trade Name:**

  ZMR™ Hip System-Porous Revision

- **Common Name:**

  Femoral Hip Prosthesis

- **Classification Name:**

  Hip joint metal/polymer semiconstrained uncemented prosthesis

- **Predicate Devices:**

  - *Impact*™ Modular Total Hip System, manufactured by Biomet, K921274, cleared February 15, 1994
  - Coated *ZT*™ Proximal Sleeve of the *S-ROM*™ Total Hip System, manufactured by Johnson & Johnson (previously Joint Medical Products Corporation), K934412, cleared June 3, 1994
  - Mallory-Head Modular Porous Series, manufactured by Biomet, K921274, cleared February 15, 1994

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Summary of Safety and Effectiveness
(Continued)

- *ZMR*™ Hip System-Revision Taper, manufactured by Zimmer, K992667, cleared October 27, 1999

- **Device Description**

  The *ZMR* Porous Revision Hip Prosthesis is a femoral stem manufactured from *Tivanium*® (Ti-6Al-4V) Alloy and intended for cementless use in revision hip arthroplasty. This device has two modular junctions: a head/neck junction and a midstem junction. Three components are intraoperatively assembled to construct the device: a proximal segment or "body," a distal stem, and a compression nut.

- **Intended Use**

  The *ZMR* Porous Revision Hip Prosthesis is intended for revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur.

- **Comparison to Predicate Devices**

  All hip systems listed above are substantially equivalent to each other and the *ZMR* Porous Revision Hip Prosthesis 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 feature a Morse-type proximal neck taper that mates with 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. All predicate devices are manufactured from metal alloys that have a history of successful clinical use in orthopaedic applications.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 3 2012

Zimmer, Inc.
% Mr. Daniel Williman
Associate Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K994286
Trade/Device Name: ZMR™ Hip System Porous Revision
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, LZO, LWJ
Dated: December 17, 1999
Received: December 20, 1999

Dear Mr. Williman:

This letter corrects our substantially equivalent letter of March 10, 2000.

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 (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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic, and
Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K994286

Device Name:

ZMR® Hip System – Porous Revision

Indications for Use:

The *ZMR* Hip System is indicated for cementless revision hip arthroplasty. Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief or when there is progressive disability.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K994286