zimmer

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K972690

OCT 15 1997

Summary of Safety and Effectiveness
22 mm Zirconia Ceramic Femoral Head, 12/14 Taper

- **Submitted By:**

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

- **Contact Person:**

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

  July 9, 1997

- **Trade Name:**

  Zirconia Ceramic Femoral Head

- **Common Name:**

  Femoral head for total hip joint prosthesis

- **Classification Name:**

  Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis, 21 CFR 888.3353

- **Predicate Devices:**

  - *Zimmer*® Zirconia Ceramic Femoral Head, K944601 and K955877, cleared January 12, 1995, and October 8, 1996, respectively.

  - Astel Cobalt-Chrome Femoral Heads, manufactured by Zimmer, K901480 and K901594, cleared June 12, 1990, and August 3, 1990, respectively.

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(Continued)

- *Zimmer*® Cobalt-Chrome Femoral Heads, described in the premarket notification for the Beta System, K953337, cleared January 22, 1996.

- Zirconia Ceramic Femoral Head, 12/14 Taper, K971752, currently being reviewed by FDA.

- **Device Description:**

  The 22 mm Zirconia Ceramic Femoral Head is made from yttria stabilized zirconium oxide (ZrO_2) ceramic and provides an alternative to cobalt-chrome alloy femoral heads. The Zirconia Ceramic Femoral Head is intended for mating with either a *Tivanium*® Ti-6Al-4V Alloy or *Zimaloy*® Cobalt-Chrome-Molybdenum Alloy modular femoral stem equipped with a tapered neck of identical dimensions. The Zirconia Ceramic Femoral Head is designed to articulate upon the UHMWPE-bearing surface of an acetabular component.

- **Intended Use:**

  The 22 mm Zirconia Ceramic Femoral Head is designed to be implanted into the human hip as a component in total hip arthroplasty and is indicated for the following:

  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 previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

- **Comparison to Predicate Devices:**

  The 22 mm Zirconia Ceramic Femoral Head is substantially equivalent to the femoral heads listed above as predicate devices. Each is designed to function as the modular femoral head component of a total hip prosthesis, is impacted onto the proximal taper of a femoral stem at the time of surgery, and articulates upon the UHMWPE-bearing surface of an acetabular component.

  The 22 mm Zirconia Ceramic Femoral Head, 12/14 taper, the previously cleared *Zimmer* Zirconia Ceramic Femoral Head, and K971752 (currently being reviewed by FDA) are made from zirconium oxide ceramic. The size range for the Zirconia Ceramic Femoral Head (12/14 taper) includes 22, 26, 28, and 32 mm diameters. The

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Zimmer Zirconia Ceramic Femoral Head is provided in 22, 26, and 28 mm diameters and supports a different taper for impaction upon the femoral stem component.

- **Clinical and Nonclinical Data**

Ceramic materials have been successfully used in orthopaedic applications for approximately 20 years. These materials exhibit excellent resistance to corrosion and wear and are highly biocompatible. The yttria stabilized zirconium oxide from which the Zirconia Ceramic Femoral Head is made has a limited clinical history. Although mechanical testing demonstrates that when used with polyethylene acetabular cups, the zirconia ceramic femoral head produces a relatively low amount of particulates, the total amount of particulate produced remains undetermined. Because of limited clinical and preclinical experience, the long-term biological effects of these particulates are unknown. Clinical investigation of the zirconium oxide ceramic prosthesis is ongoing.

RA07701K.510

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 15 1997

Re: K972690
Zirconia Ceramic Femoral Head - 22 mm
Regulatory Class: II
Product Code: LZO
Dated: July 9, 1997
Received: July 17, 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 and the following limitation that the package insert must reflect that the Zimmer Biomechanics Zirconia Ceramic Femoral Head is to only be used with the Zimmer Biomechanics 12/14 taper made from *Tivanium* Ti-6-Al-4V Alloy or cobal chrome alloy. This information must be identified in the package insert.

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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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 at (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 I

510(k) Number (if known): K972690

Device Name: 22 mm Zirconia Ceramic Femoral Head, 12/14 Taper

Indications for Use:

The 22 mm Zirconia Ceramic Femoral Head, 12/14 Taper is designed to be implanted into the human hip as a component in total hip arthroplasty and is indicated for the following:

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 previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute 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 X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

RA02650K.FM

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K97 2690