K980711

zimmer

NOV 12 1998

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:**

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  Senior Regulatory Affairs Associate
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- **Date:**

  February 23, 1998

- **Trade Name:**

  Harris/Galante Porous Hip Prosthesis With HA/TCP Coating

- **Common Name:**

  Femoral Hip Prosthesis

- **Classification Name:**

  Hip Joint Metal/Polymer/Metal Semiconstrained Porous-Coated Uncemented Prosthesis

  Stems:

  - Harris/Galante Porous Hip Prosthesis, K-840643, cleared April 17, 1984

- TCP-Coated Porocoat AML Femoral Hip Prosthesis, K-964650, cleared June 6, 1997

Acetabular Cups:

- HGP II Acetabular Stem, K-921308, cleared February 22, 1994
- Inter-Op HA Porous Acetabular System, K-972393, cleared September 19, 1997

- **Device Description**

The hydroxyapatite tricalcium phosphate coated HGP Total Hip System is modular in design and consists of four basic components: The hip stem, the femoral head, the acetabular component and the liner. The Acetabular Components also have an HA/TCP coating.

The HGP Total Hip is a femoral component made from *Tivanium*® Ti-6Al-4V Alloy. The femoral stem is straight and similar to that of other conventional total hip stems. In addition, commercially pure titanium fiber pads of approximately 2 mm thickness are metallurgically bonded to the anterior, posterior, lateral and medial aspects of the stem body.

The proximal one-third of the stem is coated with HA/TCP which is applied by a plasma spraying process. This coating is approximately 20 to 50 microns in thickness. The plasma spray feedstock and resultant coating consists predominantly of calcium hydroxyapatite with minor components of beta-tricalcium phosphate and other calcium phosphates.

The modular connection of the femoral stem is a Morse type 6° taper designed to mate with the corresponding 6° bore of a femoral head component. The femoral heads are available in 22, 26, 28, and 32 mm diameters. The modular nature of the system allows for the use of a variety of neck lengths, offsets, and femoral head diameters. The devices may also be used with endoprostheses.

This ceramic is colorless. The measurement of a calcium phosphate ceramic's chemical composition involves determination of the calcium/phosphorus ratio and trace metals content by elemental analysis. The distribution among different crystalline phases is determined by powder X-ray diffraction, which has an accuracy of approximately 10 percent for any given phase in a multiphasic, moderately crystalline calcium phosphate ceramic.

The device is designed to fit the upper end of the femur and provide an

interference fit with intimate contact between the porous titanium pads and the surrounding bone. This fibrous titanium mesh HA/TCP surface has a porous morphology which provides a scaffold-like structure into which biological tissues may ingrow, thus fixing or anchoring the prosthesis.

- **Intended Use/Indications**

Total Hip Replacement:

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 endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

Hemi-Hip Replacement:

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 femoral neck fractures in the aged; nonunion of femoral neck 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**

All hip systems listed above are substantially equivalent to each other and the HGP 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 porous or roughened surface and are modular in design. Each has 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 and the HGP Hip Prosthesis are manufactured from metal alloys that have a history of successful clinical use in orthopaedic applications.

- **Clinical and Nonclinical Data**

The HGP Hip Prosthesis is an example of a device designed to achieve biologic fixation to bone through bone ingrowth.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1998

Toni R. Kingsley, Ph.D.
Director, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K980711
Harris/Galante Hip System with *Calicoat*® Ceramic Coating
Regulatory Class: II
Product Codes: LPH and MEH
Dated: August 19, 1998
Received: August 21, 1998

Dear Dr. Kingsley:

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). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

> You may not label or in any way promote these devices for "enhanced clinical or radiographic performance, enhanced biological fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional porous coated hip prosthesis (i.e., biological fixation, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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. 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 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for 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 V

Indications for Use

510(k) Number (if known): K980711

Device Name: Harris/Galante Porous Hip Prosthesis with HA/TCP Coating

Indications for Use:

The Harris/Galante Hip Prosthesis is designed for implantation into the human joint in total hip or hemi-hip replacement and is indicated for the following:

Total Hip Replacement:

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 endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

Hemi-Hip Replacement:

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 femoral neck fractures in the aged; nonunion of femoral neck 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)

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

RA12702K.510

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980711