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## Summary of Safety and Effectiveness

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|---|---|
| **Submitter:** | Zimmer, Inc.<br>P.O. Box 708<br>Warsaw, IN 46581-0708 |
| **Contact Person:** | Karen Cain<br>Manager, Regulatory Affairs<br>Telephone: (574) 372-4219<br>Fax: (574) 372-4605 |
| **Date:** | March 3, 2003 |
| **Trade Name:** | Alumina Ceramic Femoral Heads, 28 and 32 mm |
| **Common Name:** | Ceramic Femoral Head Prosthesis |
| **Classification Name and Reference:** | Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis<br>21 CFR § 888.3353 |
| **Predicate Devices:** | Zimmer Ceramic Femoral Heads, K905739 and K914676, cleared March 7, 1991, and January 13, 1992, respectively. |
| **Device Description:** | The Alumina Ceramic Femoral Heads are single-use devices manufactured from $Al_2O_3$. Both 28 and 32 mm diameter heads are available in three neck lengths each. The 12/14 bore of the ceramic ball mates with Zimmer titanium and cobalt-chromium alloy femoral stems having a corresponding 12/14 neck taper. |
| **Indications for Use:** | The Alumina Ceramic Femoral Heads are modular components designed for use in total hip arthroplasty and indicated for the following:<br><br>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 |

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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 Device:**

The Alumina Ceramic Femoral Heads are substantially equivalent to the femoral heads listed above as predicate devices. Both designs are intended to function as a modular femoral head component in hip arthroplasty and are manufactured from $Al_2O_3$ ceramic.

**Performance Data:**

Mechanical testing was performed per the FDA *Draft Guidance for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems.* Test results indicate that the Alumina Ceramic Femoral Heads are equivalent to devices currently on the market and capable of withstanding *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2003

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

Re: K030724
Trade/Device Name: Alumina Ceramic Femoral Heads, 28 and 32 mm
Regulation Numbers: 21 CFR 888.3353
Regulation Names: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Codes: LZO
Dated: March 3, 2003
Received: March 7, 2003

Dear Ms. Cain:

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.

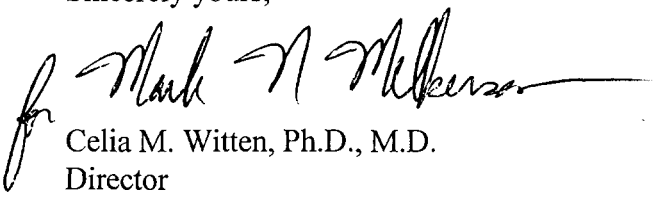
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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):** K030724

**Device Name:**

Alumina Ceramic Femoral Heads, 28 and 32 mm

**Indications for Use:**

The Alumina Ceramic Femoral Heads are modular components designed for use in total hip arthroplasty and 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)

for Mark N. Melkerson

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

510(k) Number K030724

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