

K973307

NOV 20 1997

**Summary of Safety and Effectiveness Data for the
S-ROM[®] Zirconia Ceramic Femoral Head**

**Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350**

Contact Person

Mary E. Gray
Associate Regulatory Affairs Specialist
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Name of Device

Proprietary Name: S-ROM Zirconia Ceramic Femoral Head
Common Name: Hip Prosthesis
Classification Name: Hip joint metal/ceramic/polymer semi-constrained
cemented or nonporous uncemented prosthesis.
Regulatory Class: Class II by 21 CFR 888.3353
Product Code: 87 LZ0
Owner/Operator No.: 9001269

Device Classification

This device has been placed in Class II for Hip joint metal/ ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR § 888.3353.

Statement of Substantial Equivalence

The S-ROM Zirconia Ceramic Hip Head is identical in material (PROZYR[®]) and in function (indicated use) to the P.F.C. Zirconia Ceramic Hip Head cleared for marketing under premarket notifications K# 962248 (August 29, 1996)/ K# 933275 (September 28, 1994).

The S-ROM Zirconia Ceramic Hip Head is identical in design (drawing specifications) and function (indicated use) to the S-ROM Zirconia Ceramic Hip Head cleared for marketing under premarket notification K# 921111.

The subject device is composed of similar materials to the predicate device mentioned above (P.F.C. Zirconia Ceramic Hip Head). Further, the intended use and the manufacture of the S-ROM Zirconia Ceramic Hip Head are substantially equivalent to those already cleared for domestic commercial distribution.

Additionally, the packaging and method of sterilization utilized for the S-ROM Zirconia Ceramic Hip Head are the same as those used for the previously mentioned predicate device.

Indications for Use

The S-ROM Zirconia Ceramic Hip Head is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, traumatic and non-union of femoral fractures. Use of the prosthesis is also indicated for revision of previous hip arthroplasty and for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped femoral epiphysis, and disability due to previous fusion.

Physical Description

The S-ROM Zirconia Ceramic hip head is manufactured of Yttrium Stabilized Zirconium Oxide (Zirconia), also known as PROZYR®. The S-ROM ceramic hip heads are designed to be used with the S-ROM Total Hip System femoral stems.

The ceramic femoral heads are contraindicated for use with any acetabular components other than an UHMWPE cup or metal backed UHMWPE cup.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 1997

Ms. Mary E. Gray
Associate Regulatory Affairs Specialist
Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K973307
S-ROM® Zirconia Ceramic Femoral Hip Head for Use
with the S-ROM® Total Hip System
Regulatory Class: II
Product Code: LZO
Dated: September 2, 1997
Received: September 3, 1997

Dear Ms. Gray:

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 S-ROM Zirconia Ceramic Femoral Hip Heads are to be used only with titanium alloy (Ti6Al4V) hip stems with the 11/13 Morse taper trunnions.

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.

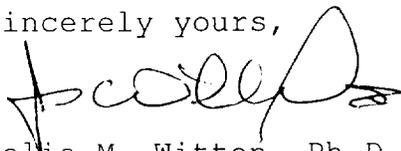
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


f 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

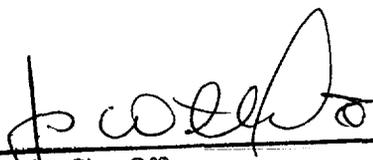
**Indications for Use
for the
S-ROM® Zirconia Ceramic Femoral Head**

**Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350**

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Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)

Division of General Restorative Devices

§10(k) Number K973307