K980081

Summary of Safety and Effectiveness Data for the S-ROM® Zirconia Ceramic Femoral Head Use with Cobalt-Chromium-Molybdenum Alloy 11/13 Morse-Taper Femoral Stems

APR - 9 1998

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

Contact Person

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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 LZO
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 Femoral Head is identical in design (drawing specifications) to the S-ROM Zirconia Ceramic Femoral Head cleared for marketing under premarket notification K973307 (November 20, 1997) for use with titanium alloy femoral components. The S-ROM Zirconia Ceramic Femoral Head is identical in material (PROZYR® or ZYRANOX™) to the S-ROM Zirconia Ceramic Femoral Head cleared for marketing under premarket notifications K973307 and K921111.

The subject device is to be utilized with the same 11/13 Morse-taper femoral components as the predicate device mentioned above (S-ROM Zirconia Ceramic Femoral Head). The difference between the femoral stems which will be utilized is the material composition of either titanium or cobalt-chromium alloy.

Indications for Use

The S-ROM Zirconia Ceramic Femoral 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, 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 femoral head is manufactured of either Yttrium Stabilized Zirconium Oxide (Zirconia), also known as PROZYR® or ZYRANOX™ zirconia ceramic. The S-ROM ceramic femoral head is designed to be used with 11/13 Morse-taper femoral stems composed of either titanium alloy or cobalt-chromium alloy.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 1998

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

Re: K980081
S-ROM® Zirconia Ceramic Femoral Hip Head
Regulatory Class: II
Product Code: LZO
Dated: January 8, 1998
Received: January 9, 1998

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 Heads are to be used only with cobalt-chrome or Ti-6Al-4V - alloy hip stems with the Johnson and Johnson Professional, Inc. 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,

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 for Use
with Cobalt-Chromium-Molybdenum (Co-Cr-Mo) Alloy
11/13 Morse-Taper Femoral Stems

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Indications of Use

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Prescription Use _____ X _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K98008