

1K935921

NOV 28 1994

**SUMMARY OF SAFETY AND EFFECTIVENESS**

Smith & Nephew Richards Inc. is submitting a premarket notification for the Zirconia Ceramic Femoral Head. The device is identical to the zirconia ceramic femoral heads previously submitted by Smith & Nephew Richards to the FDA with the exception of a change in the manufacturing vendor.

SA356207/1

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 28 1994

Food and Drug Administration  
1390 Piccard Drive  
Rockville MD 20850

Mr. Thomas L. Craig  
Director - Regulatory Affairs  
Smith & Nephew Richards, Inc.  
1450 Brooks Road  
Memphis, Tennessee 38116

Re: K935921  
Zirconia Ceramic Femoral Head  
Regulatory Class: II  
Product Code: LZ0  
Dated: November 12, 1994  
Received: November 17, 1994

Dear Mr. Craig:

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 to devices marketed in interstate commerce prior to May 28, 1976 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 upon the use of the AstroMet AmZirOx balls with the stems listed below:

<u>Stem</u>	<u>510(k) #</u>	<u>Stem Material</u>	<u>Material Standard</u>
Bio-Fit	K854791	CoCr	(ASTM F 75)
Opti-Fix	K860635, R921400	Ti-6Al-4V	(ISO 5832/III)
Spectron	K823727, R823722	CoCr	(ASTM F 799)
HJD	K881117	Ti-6Al-4V	(ISO 5932/III)
Ti-Fit	K873797	Ti-6Al-4V	(ISO 5832/III)
Tri-Wedge (Hartford)	K870128, K921400	Ti-6Al-4V	(ISO 5832/III)
International	K862225	Ti-6Al-4V	(ISO 5832/III)
Modular Hip System	K900628, K921400	Ti-6Al-4V	(ISO 5832/III)
Modular Hip System	K912593	CoCr	(ASTM F 75)
RMHS Monolithic	K923275	Ti-6Al-4V	(ISO 5832/III)

You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitations:

1. The contraindications of the labeling must include: "The Zirconia Ceramic Head is contraindicated for use with any other than an UHMWPE cup or a metal backed UHMWPE cup."
2. The Warnings and Precautions of the labeling must include: "The Zirconia Ceramic Head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that, when used with polyethylene acetabular cups, the partially stabilized Zirconium ball produces a relatively low amount of particulates, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the long term biological effects of these particulates are unknown."
3. The stems identified above are labeled for use with the following Zirconia Ceramic Heads:

<u>Cat.No.</u>	<u>DiameterNeck Length</u>
42-7814	32mm Short
42-7815	32mm Standard
42-7816	32mm Long
42-7817	32mm X-Long
42-7818	28mm Standard
42-7819	28mm Long
42-7820	28mm X-Long
42-7821	26mm Long
42-7822	26mm X-Long

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.

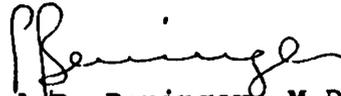
If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.



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This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Paul R. Beninger, M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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