JUN 2 6 2002

K021799 page 1 of 1

BIOMET

CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0578

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist
Phone: (574) 267-6639
Fax: (574) 372-1790

Trade Name: Cemented Femoral Head Resurfacing Device

Common Name: Hemi-hip

Classification Name: Hip joint femoral (hemi-hip) metallic resurfacing prosthesis (21 CFR 888.3400)

Legally Marketed Device to which Substantial Equivalence is claimed: The current device is a modification of the Nelson resurfacing Head cleared by 510(k) K983452.

Device Description: The Cemented Femoral Head Resurfacing device is designed to replace the outer surface of the femoral head while preserving as much natural bone as possible. The device retains the diameter of the natural femoral head and articulates against the natural acetabulum (hemi-hip).

The device is manufactured from cobalt alloy (Co-Cr-Mo) conforming to ASTM F-75. It has a highly polished outer surface and a grit blasted (roughened) inner surface identical to the predicate device. A central post has been added for stabilization. The modified device is available in diameters of form 38mm to 60mm, in one-millimeter increments.

Intended Use: Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis and rheumatoid arthritis.

Summary of Technologies: The materials, surface finishes and processing of the Cemented Femoral Head Resurfacing Device are similar to the predicate.

Non-Clinical and Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2002

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Orthopedic, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K021799
Trade/Device Name: Cemented Femoral Head Resurfacing Device
Regulation Number: 21 CFR 888.3400
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Resurfacing Prosthesis
Regulatory Class: Class II
Product Code: KXA
Dated: May 29, 2002
Received: May 31, 2002

Dear Ms. Beres:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Melkerson

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

510(k) Number (if known): K021799

Device Name: Cemented Femoral Head Resurfacing Device

Indications For Use:

a) Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis
b) Rheumatoid arthritis

The device is a single use implant intended for use with bone cement

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021799

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)