JUL 30 1999

K991708

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, IN 46581-0587

Contact Person: Dalene Hufziger Binkley

Trade Name: Zirconia 22.22mm Ceramic Modular Head

Classification Name: Hip joint metal/ceramic/polymer semiconstrained cemented or non-cemented prosthesis.

Intended Use: The Zirconia 22.22 mm Ceramic Modular Head can be used for noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, correction of functional deformity, and revision of failed hip arthroplasty.

Device Description: The Biomet ceramic modular head is designed to be the articular surface of an artificial hip joint. The highly polished spherical surface articulates with a polyethylene lined cup. The ball attaches to a metallic femoral stem. These heads are compatible with all of Biomet's hip stems with Type I (4° 0' ± 0° 2') tapers. The metallic stems are manufactured from either titanium alloy (Ti-6Al-4V) conforming to ASTM F-136 or cobalt alloy (Co-Cr-Mo) conforming to either ASTM F-799. This submission covers 22.22 mm diameter heads with –3 and standard neck offsets.

Biomet Zirconia Ceramic Modular Heads are manufactured from Yttria Stabilized Zirconia. Manufacturing of these ceramic devices will be done entirely outside Biomet by Norton Advanced Ceramics. Mechanical testing was conducted with the final taper design in accordance with the FDA's guideline document. Devices were found to conform to all requirements including compression, pull-off and fatigue strength.

Potential Risks: The potential risks associated with this device are the same as with any hip replacement device. These include, but are not limited to:

Nerve Damage	Material Sensitivity	Bone Fracture
Blood Vessel Damage	Deformity of the Joint	Excessive Wear
Cardiovascular Disorders	Muscle Laxity	Infection
Delayed Would Healing	Soft Tissue	Imbalance
Fatigue Fracture of Component	Subluxation	Hematoma
Component Migration/Loosening	Dislocation	

Substantial Equivalence: The Zirconia 22.22 mm Ceramic Modular Heads from Norton Advanced Ceramics are substantially equivalent to other ceramic heads on the market. A predicate to the 22.22 mm head is the Zirconia 28 mm Ceramic Modular Head also by Norton (K964431).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

Ms. Dalene Hufziger Binkley
Regulatory Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K991708
Trade Name: Zirconia 22.22mm Ceramic Modular Head
Regulatory Class: II
Product Code: LZO
Dated: May 10, 1999
Received: May 19, 1999

Dear Ms. Binkley:

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 control provisions of the Act. The general control 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. 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 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 at (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

510 (k) NUMBER (IF KNOWN): K991708

DEVICE NAME: Zirconia 22.22mm Ceramic Modular Heads

INDICATIONS FOR USE:

The indications for use of the Zirconia Ceramic Modular Heads include: 1) noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis, 2) rheumatoid arthritis, 3) correction of functional deformity, and 4) revision of failed hip arthroplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (Per 21 CFR 801.109) OR Over-The-Counter-Use No (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991708