



AUG 11 1997

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K964431

Summary of Safety and Effectiveness Information

Product: Zirconia Ceramic Modular Heads (Norton Advanced Ceramics)

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 tapers. This submission covers 28mm diameter heads with various 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. Zirconia has been shown to possess superior wear qualities in comparison to all metals and even alumina 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 Wound Healing | Soft Tissue | Imbalance |
| Fatigue Fracture of Component | Subluxation | Hematoma |
| Component Migration/Loosening | Dislocation | |

Substantially Equivalent Devices:

- Zirconia Ceramic Heads (Type I Taper) (Biomet, Warsaw, IN)
- Zirconia Femoral Heads (Smith & Nephew Richards, Memphis, TN)
- BioloX® Al₂O₃ Ceramic Femoral Heads (Dow Corning Wright, Arlington, TN)
- BioloX® Al₂O₃ Ceramic Femoral Heads (Smith and Nephew Richards, Memphis, TN)
- Modular Ceramic Heads (DePuy, Warsaw, IN)
- Modular Ceramic Heads (Thackray, Orlando, FL)
- Modular Ceramic Heads (Protek, Indianapolis, IN)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Sandborn Beres
Director, Regulatory Affairs
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

AUG 11 1997

Re: K964431
Zirconia Ceramic Modular Heads
(Norton Advanced Ceramics)
Regulatory Class: II
Product Code: LZO
Dated: June 24, 1997
Received: June 27, 1997

Dear Ms. Beres:

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 Zirconia Ceramic Modular Heads (Norton Advanced Ceramics) are to be used only with cobalt-chrome-molybdenum and Ti6Al4V alloy hip stems with the Type I taper ($4^{\circ}0'$, $\pm 0^{\circ}2'$) 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.

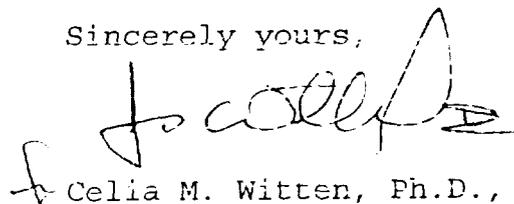
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

510(k) Number (if known): K964431

Device Name: Zirconia Ceramic Modular Heads (Norton Advanced Ceramics)

Indications For Use:

The Zirconia Ceramic Modular Heads (Norton Advanced Ceramics) are indicated for use in Non-inflammatory Degenerative Joint Disease including osteoarthritis and avascular necrosis, Rheumatoid Arthritis, correction of functional deformity, and revision of failed hip arthroplasty.

This device is a single use Implant.

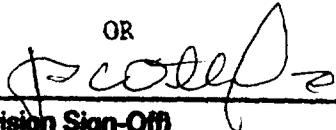
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



(Optional Format 1-2-96)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K964431