

OCT 21 1999



### Summary of Safety and Effectiveness

**Device Name:** Bio-Modular Shoulder Offset Humeral Heads

**Classification Name:**

- 1) Shoulder joint metal/polymer semi-constrained cemented prosthesis (Section 888.3660)
- 2) Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (Section 888.3690)

**Device Classification and Product Codes:**

- 1) Pre-amendment Class III (proposed reclassification to class II, published March 15, 1999) KWS
- 2) Class II HSD

**Intended Use:** The Bio-Modular Shoulder System is intended for partial or total shoulder joint arthroplasty.

**Indications for use:**

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- 2) Rheumatoid arthritis
- 3) Revision where other devices or treatments have failed
- 4) Correction of functional deformity
- 5) Treatment of acute fracture of the humeral head unmanageable using other treatment methods.
- 6) Cuff tear arthropathy

**Device Description:** Offset Humeral Heads are a modification of standard modular heads. Rather than a modular head with a centered stem providing the same amount of bearing surface circumferentially from the stem, the stem is placed 5 degrees off the center point of the head providing a greater amount of bearing surface. This gives the surgeon the ability to more closely reconstruct the natural anatomy of the patient's shoulder and potentially reduce the risk of dislocation. In order to replicate trial orientation of the Offset Humeral Head, an alignment pin is provided which fits into a hole in the humeral stem and then may be aligned with one of 8 holes on the under surface of the head. The Bio-Modular Offset Humeral Heads are manufactured from cobalt alloy (Co-Cr-Mo) conforming to ASTM F-1537.

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biomet@biomet.com

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

Reaction to the bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disorders	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive wear
Nerve damage	Disassociation of the modular head	

**Substantial Equivalence:** Biomet's Bio-Modular Shoulder Offset Humeral Heads are substantially equivalent to other shoulder devices on the market. Specifically, the device may be compared to :

Bio-Modular Shoulder System (Biomet, Inc.)	510(k) K872454
Aequalis Shoulder Prosthesis (Tornier, Inc.)	510(k) K952928
Global Dialable Eccentric Head (DePuy)	510(k) K974044



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 21 1999

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

Re: K992899  
Trade Name: Bio-Modular Offset Humeral Heads  
Regulatory Class: III  
Product Code: KWS and HSD  
Dated: August 26, 1999  
Received: August 30, 1999

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 enclosures) 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. 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.

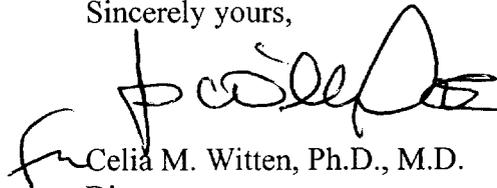
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 – Ms. Patricia Sandborn Beres

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) 594-4595. 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

510(k) Number (if known): K992899

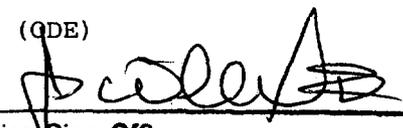
Device Name: Bio-Modular Shoulder Offset Humeral Heads

**Indications For Use:**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of **General Restorative Devices**

510(k) Number K992899

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)