

K99 1585

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**Sponsor:** Biomet, Inc.  
Airport Industrial Park  
Warsaw, Indiana 46580

**Device:** Biomet

**Classification Name:** Shoulder joint humeral (hemi-shoulder) metallic prosthesis

**Intended Use:** Biomet's Bipolar Shoulder Prosthesis is indicated for use in most cases where a conventional shoulder hemi-arthroplasty would be indicated. Typical indications include osteoarthritis, avascular necrosis, traumatic arthritis, rheumatoid arthritis, correction of severe functional deformity, revision procedures where other treatments or devices have failed, fracture, and cuff tear arthropathy.

This device is a single use implant intended for cemented application only. It is intended for use with Biomet's humeral components previously cleared by the FDA for cemented application.

**Device Description:** The Bipolar Shoulder Prosthesis is a self retaining humeral shell. The outer surface of the shell is highly polished. The inner polyethylene liner is preassembled with the outer metallic shell. A polyethylene retaining ring is inserted into the shell at the time of surgery to capture a specially designed modular head component.

The shell is available in four outer diameters, 40mm through 52mm. The modular head components are available in various neck lengths to correct laxity in the joint. Two types of modular heads are available to correspond with the geometry of the humeral stems.

The device is designed to articulate with the natural glenoid surface eliminating the need for a separate glenoid component similar to a hemi-arthroplasty. Potentially a greater range of motion can be obtained with this device because of its bi-rotational nature.

**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 bone cement     | Bone fracture       |
| Fracture of the components  | Hematoma            |
| Cardiovascular disorders    | Blood vessel damage |
| Implant loosening/migration | Nerve damage        |
| Soft tissue imbalance       | Excessive wear      |
| Deformity of the joint      | Infection           |
| Delayed wound healing       | Metal sensitivity   |
| Fracture of the cement      | Dislocation         |
| Breakdown of porous surface |                     |

**Substantial Equivalence:** In function and overall design the Bipolar Shoulder Prosthesis is equivalent to other commercially available shoulder hemi-arthroplasties currently on the market. These devices include:

New Jersey Hemi Shoulder (DePuy, 510(k) K800494)  
Monospherical Shoulder (Howmedica, 510(k) K802123)  
H-J-B Shoulder (Richards, pre-amendment)  
Shoulder Prosthesis (Zimmer, pre-amendment)  
Neer II Total Shoulder System (3M, pre-amendment)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 18 1999

Mr. Fred McClure  
Regulatory Specialist  
Biomet, Inc.  
Airport Industrial Park  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K991585  
Trade Name: Bipolar Shoulder Prosthesis  
Regulatory Class: III  
Product Code: KWT, MJT  
Dated: May 5, 1999  
Received: May 7, 1999

Dear Mr. McClure:

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.

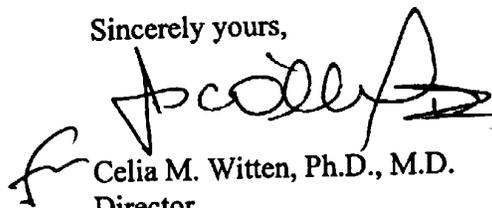
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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 (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', with a large, stylized initial 'C' and 'W'.

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

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510 (k) Number (if known) : \_\_\_\_\_

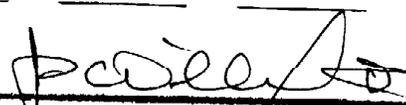
Device Name: Bipolar Shoulder Prosthesis

Indications For Use: Biomet's Bipolar Shoulder Prosthesis is indicated for use in most cases where a conventional shoulder arthroplasty would be indicated. Typical indications include osteoarthritis, avascular necrosis, traumatic arthritis, rheumatoid arthritis, correction of severe functional deformity, revision procedures where other treatments or devices have failed, fracture, and cuff tear arthropathy.

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

Prescription Use X  
(Per 21 CFR 801.109)

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

K991585

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