

MAY 5 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

K980428

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

**Device:** Biomet Biaxial Total Elbow

**Classification Name:** Elbow joint metal/polymer constrained cemented prosthesis. (888.3150)

**Intended Use:** The Biomet Biaxial Total Elbow is indicated for use in Rheumatoid Arthritis, Non-Inflammatory Degenerative Joint Disease including Osteoarthritis and Avascular Necrosis, correction of severe functional deformity, revision procedures where other treatments or devices have failed., and treatment of acute or chronic fractures with humeral epicondyle involvement which are unmanageable using other treatment methods. This linked constrained elbow prosthesis is indicated for joints with both intact and limited soft tissue structures about the elbow.

This device is a single use implant. It is intended for use with bone cement.

**Device Description:** The Biomet Biaxial Total Elbow Prosthesis is a constrained hinge elbow prosthesis used to replace the humeral-ulnar articulation of the human elbow. The implant consists of two main components, an ulnar and a humeral component which are joined by a modular connecting piece.

The biaxial elbow is a "loose hinge" type that has a parallel acting second axis of articulation between the ulnar and humeral stems. An inherent characteristic of the biaxial articulation is that it can vary the anterior-posterior offset between the intramedullary stems. The Biaxial Elbow allows the stem offset to vary because of varying amounts of flexion between the displaced axes of the prosthesis.

The humeral component is a titanium alloy stem. The humeral stem incorporates a flange on the anterior side for additional fixation. A portion of the stem and flange are plasma sprayed coated. The remainder of the stem is a bead blast finish. The humeral component utilizes a polyethylene humeral bearing (saddle bearing) to prevent metal on metal contact with the connecting segment.

The ulnar component is titanium alloy stem. A portion of the surface of the ulnar component is textured with a thin layer of Biomet's plasma spray coating (Bondcoat) and the remainder is a bead blast finish. The ulnar component utilizes a polyethylene ulnar bearing (saddle bearing) to prevent metal on metal contact with the connecting segment.

The modular connecting segment is a cobalt chromium alloy metallic piece with a polished finish. The connecting segment is joined to the humeral and ulnar stems by means of a sleeve bearing metal reinforcing rod and saddle bearing. The metal

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reinforcing rod or axle assembly is manufactured from cobalt chromium. The axles are sleeved by axle bearings, which are manufactured from ArCom® (ultra high molecular weight polyethylene (UHMWPE)). The axle retaining clips are manufactured from titanium alloy. The saddle bearings of the humeral and ulnar component are manufactured from Arcom.

**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	Breakdown of porous surface
Dislocation	

**Substantial Equivalence:** In function and overall design Biomet's Biaxial Total Elbow is equivalent to almost all elbow joint metal/polymer constrained cemented prostheses on the market. Predicate devices include:

Coonrad III Total Elbow (Zimmer, 510(k) #K883665)  
Osteonics Elbow Prosthesis (Osteonics Corp., 510(k) #K861680)

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Deborah M. Matarazzo R.N., B.S.N.  
Clinical Research Specialist  
Biomet, Inc.  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K980428  
Trade Name: Biomet Biaxial Total Elbow  
Regulatory Class: III  
Product Code: JDC  
Dated: January 29, 1998  
Received: February 4, 1998

Dear Ms. Matarazzo:

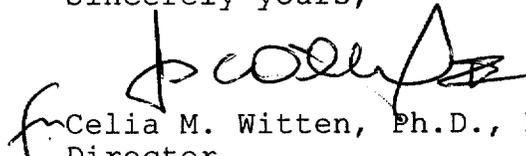
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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. 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 (Pre-market 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 pre-market 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,



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): K980428

Device Name: Biomet Biaxial Total Elbow

**Indications For Use:** The Biaxial Hinge Total Elbow is indicated for use in Rheumatoid Arthritis, Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, correction of severe functional deformity, revision procedures where other treatments or devices have failed, and treatment of acute or chronic fractures with humeral epicondyle involvement which are unmanageable using other treatment methods. This linked constrained elbow prosthesis is indicated for joints with both intact and limited soft tissue structure about the elbow.

This device is a single use implant. It is intended for use with bone cement.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

[Signature]  
(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number K980428