

AUG 11 1998

K982398  
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**SUMMARY OF SAFETY AND EFFECTIVENESS**

**Sponsor:** Biomet, Inc.  
Airport Industrial Park  
P.O. Box 587  
Warsaw, Indiana 46580

**Device:** Biomet 100% porous coated Biaxial Total Elbow

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

**Intended Use:** The Biomet 100% porous coated 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.

**Device Description:** The Biomet 100% porous coated Biaxial Hinge 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 components, an ulnar and a humeral component which are joined by a modular connecting piece.

The Biaxial 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 mechanical constraint of the articulation allows a total of 16 degrees of varus valgus movement, 6 degrees of hyperextension, and 188 degrees of flexion.

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

The ulnar component is a titanium alloy stem. The surface of the ulnar component is plasma spray coated. 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

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means of a sleeve bearing metal reinforcing rod or axle and saddle bearing. The metal reinforcing rod or axle is manufactured from cobalt chromium. The axles are sleeved by axle bearings, which are manufactured from ArCom<sup>®</sup> (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<sup>®</sup>.

**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 100% porous coated 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)  
Biaxial Total Elbow (Biomet, Inc., 510(k) #K980428)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 11 1998

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

Re: K982398  
Biomet 100% porous coated Biaxial Total Elbow  
Regulatory Class: III  
Product Code: JDC  
Dated: July 8, 1998  
Received: July 10, 1998

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 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.

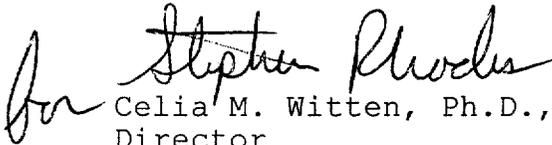
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Quality 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.

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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) : K982398

Device Name: Biomet 100% porous coated Biaxial Total Elbow

**Indications For Use:** The Biomet 100% porous coated 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.

Prescription Use X  
(Per 21 CFR 801.109)

Over-the-Counter Use \_\_\_\_\_



(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number K982398

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

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