OCT 15 1997

K972691

BIOMET INC®

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Device: ABC Total Elbow Prothesis

Classification Name: Elbow joint metal/polymer semi-constrained cemented prothesis. (888.3160)

Intended Use: The ABC (Anatomical Bone Conserving) Elbow Prothesis is indicated for use in Rheumatoid Arthritis, Non-Inflammatory degenerative join 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 device is a single use implant. It is intended for use with bone cement.

Device Description: The ABC elbow is a total elbow prothesis. The implant consists of two components, an ulna and a humeral component.

The ulna is made up of two elements, the polyethylene articulating surface and the titanium stem. The polyethylene is compression molded onto the substrate. The articulating section is formed like part of a cylinder, the inner part being the polyethylene bearing and the outer being the substrate. The ulna component is designed to match the existing trochlea anatomy. This conserves bone and will improve the ease of implant alignment and fixation.

The substrate is roughened to enhance fixation to the cement interface. The stem is shaped to approximate to the internal geometry of the proximal ulna at the trochlea. The stem may be coated with a titanium plasma spray to provide additional cement fixation. The inner surface of the implant, the polyethylene bearing, is radiused in both axes.

000097

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

OFFICE 219.267.6639 ■ FAX 219.267.8137 ■ E-MAIL biomet@biomet.com

The humeral component is a one piece cobalt chrome casting. The barrel is open ended and this matches the bone cut on the distal anterior humerus. The open section has been thickened internally to compensate for mechanical weakening caused by the removal of the closing section of the barrel. The transition from the barrel has been profiled to match the natural anatomy of the olecranon fossa. The support of the inside of the barrel and the gradual transition from barrel to stem ensure the mechanical strength of the barrel is not compromised. It requires less bone removal to implant the humeral component and the stem is designed to match the natural anatomy of the olecranon fossa and the surrounding borders.

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

Substantial Equivalence: The ABC Total Elbow Prothesis is substantially equivalent to almost all elbow devices on the market in overall design and intended function. Predicate devices include:

Sorbie-Questor Total Elbow System (Wright Medical, 510(k) #K955099)
Osteonics Elbow Prothesis (Osteonics, 510(k) #K861680)
Coonrad III Total Elbow (Zimmer, 510(k) #K883665)
Pritchard Elbow (Depuy, 510(k) #K810847)
Surface Replacement Elbow (Howmedica, 510(k) # K820957)
Capitello Condylar (Johnson & Johnson, Preamendment?)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kara Mezger
Glinical Research Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

OCT 15 1997

Re: K972691
Biomet IBC Elbow Prosthesis (Originally Submitted as ABC Total Elbow Prosthesis
Regulatory Class: II
Product Code: JDB
Dated: July 16, 1997
Received: July 17, 1997

Dear Ms. Mezger:

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 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,

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): K972691

Device Name: ABC Total Elbow Prothesis

Indications For Use:

The ABC Elbow Prothesis 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 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for CDRH Mark N Milhern
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972691