9/30/99

K983036

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Device: Single Axle Total Elbow

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

Intended Use: The Single Axle 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 Single Axle Total Elbow Prosthesis is a constrained, "sloppy-hinge" elbow device used to replace the humeral-ulnar articulation of the human elbow. The implant consists of two main components, an ulnar component and a humeral component, which are joined by an axle (refer to Exhibit III).
The Single Axle Elbow features a "sloppy-hinge" that will allow for 16 degrees of varus/valgus movement (refer to Exhibit III). A hyperextension stop (flat) is placed on the ulnar component to control the amount of hyperextension allowed by the device. The device shown in Exhibit III was designed to have 0 degrees of hyperextension, but some hyperextension may be allowed at the specific request of the surgeon. The amount of flexion of the device is approximately 137° (see Exhibit III), but this may also change somewhat due to specific patients' anatomy and surgeon requests.

The humeral component will be made of titanium alloy. Each humeral component will be custom designed for patient specific anatomy from X-rays, CT-scans, or some other media for measuring patient anatomy. In some cases the humeral component may include a replacement portion if distal humeral bone loss exists (refer to Exhibit IV). A portion of the extramedullary and intramedullary sections of the humeral component may be plasma sprayed with the remainder of the intramedullary portion having a bead blast finish. Please refer to Exhibit IV for the locations of the various surfaces and range of dimensions.

The ulnar component will be made of titanium alloy. The ulnar and humeral components will be separated by a polyethylene Saddle Bearing to prevent metal on metal contact

(refer to Exhibit III). Each ulnar component will be designed for patient specific anatomy from X-rays, CT-scans, or some other media for measuring patient anatomy. In some cases the ulnar component may include a replacement portion if proximal ulnar bone loss exists (refer to Exhibit IV). The ulnar component may also contain through slots posteriorly for the attachment of soft tissues. A portion of the extramedullary and intramedullary sections of the ulnar component may be plasma sprayed to 0.030/0.040" thick or a thinner coating (Bondcoat), with the remainder of the intramedullary portion having a bead-blast finish. Please refer to Exhibit IV for the locations of the various surfaces and range of dimensions

The humeral and ulnar components are connected by an axle bearing, metal reinforcing rod or axle and a saddle bearing. The metal reinforcing rod or axle is cobalt chromium. The axle is sleeved by an axle bearing, which is manufactured from ultra high molecular weight polyethylene (UHMWPE). The axle retaining clips are manufactured from titanium alloy. The saddle bearing is also manufactured from UHMWPE. The saddle bearing. axle bearing, and retaining clips will be consistent for all Biomet Single Hinge Elbows.

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 Single Axle Total Elbow is equivalent to almost all elbow joint metal/polymer cemented constrained prostheses on the market. Predicate devices include:

Townley Total Elbow (Biopro, 1996, 510(k) #K955916)
Osteonics Total Elbow System (Osteonics 1998, 510(k) #980502)
ABC Total Elbow Prosthesis (Biomet, Inc., 1997, 510(k) #972691)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1999

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

Re: K983036
Trade Name: Single Axle Total Elbow
Regulatory Class: III
Product Code: JDC
Dated: February 19, 1999
Received: February 22, 1999

Dear Mr. McClure:

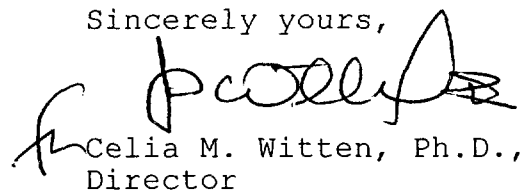
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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) : K983036

Device Name: Single Axle Total Elbow

Indications For Use: The Single Axle 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)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983036