

SEP 13 1999



Summary of Safety and Effectiveness

Proprietary Name: Bio-Modular Shoulder System

Classification Name:

- 1) Shoulder joint metal/polymer semi-constrained cemented prosthesis (Section 888.3660)
- 2) Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (Section 888.3690)

Device Classification and Product Codes:

- 1) Pre-amendment Class III (proposed reclassification to class II, published March 15, 1999) KWS
- 2) Class II HSD

Intended Use: The Bio-Modular Shoulder System is intended for partial or total shoulder joint arthroplasty. Total shoulder replacement devices are intended to be inserted with bone cement. Non-porous coated humeral stems being implanted for hemi-arthroplasty may be press fit.

Indications for Use:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Revision where other devices or treatments have failed
- 4) Correction of functional deformity
- 5) Treatment of acute fracture of the humeral head unmanageable using other treatment methods
- 6) Cuff tear arthroplasty

Device Description: The Bio-Modular Shoulder System consists of humeral stems of various lengths and porous coating levels, humeral heads of various diameters and neck lengths, and both all polyethylene and metal backed polyethylene glenoid components. Each type of component will be described individually.

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Humeral Stems: The Bio-Modular Humeral stem features a bi-planer taper to promote stress transfer down the length of the stem. This minimizes removal of endosteal bone and enhances the ease of stem insertion. Each stem has a lateral fin to provide rotational stability. Holes in the fin provide the surgeon with the option of suture attachment during fracture reconstruction. A collar minimizes subsidence. Stems are available in a primary length of 115mm in 1mm incremental stem diameters from 6 to 17mm. Longer stems (190mm) are available in 2mm incremental diameters from 7 to 13mm.

Humeral stems are available in either an Interlok (grit blasted) finish or with plasma spray porous coating. Porous stems are circumferentially porous coated proximally to enhance cement fixation. Centering sleeves are available to assist in stem alignment during cementing.

Humeral Heads: All humeral stems feature a reverse Morse taper for attachment of the modular humeral head. This means that instead of the tapered post being on the humeral stem like traditional devices, the post is on the modular head and the bore is in the stem. The advantage of the reverse taper configuration is that it allows for maximum exposure of the glenoid when the stem is in place. Therefore, the humeral stem may be implanted prior to glenoid resurfacing. Humeral heads are available in a variety of diameters and neck lengths. In addition to the standard symmetrical bearing surface, heads are available with articular extensions to enhance component stability.

Glenoid Components: Although the humeral stem and head may be implanted as a hemi-shoulder replacement, glenoid components are available for total shoulder replacement. All polyethylene glenoid components come in two styles. The keeled component features a triangular keel that may be trimmed for better fit during surgery. This style is available in 3 sizes and 2 thicknesses. The second style features 3 pegs to assist in fixation and is available in 3 sizes and 1 thickness. Both styles have an embedded x-ray marker.

A modular, porous coated, metal backed glenoid component provides distribution of stresses into the cement. The device features a central tapered peg and the option of screw fixation.

Substantial Equivalence

- Bio-Modular Shoulder (Biomet, Inc.)
- Integrated Shoulder System (Kirschner)
- Gobal Shoulder (DePuy)
- Foundation Shoulder System (Encore Orthopedics)



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K992119
Trade Name: Bio-Modular Shoulder System
Regulatory Class: III
Product Code: KWS and HSD
Dated: June 21, 1999
Received: June 23, 1999

Dear Ms. Beres:

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.

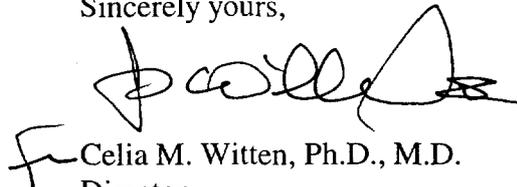
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized initial 'F' to the left.

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): K992119

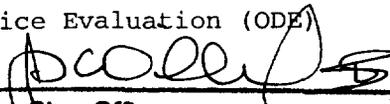
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992119

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)