DEC 2 1998

K983710

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Device: Bi-Metric CoCr Head/Neck Color Buff Replacement Hip Stem

Classification Name: Hip joint metal/polymer/metal semi-constrained cemented prosthesis

Intended Use: Biomet's Bi-Metric CoCr Head/Neck Color Buff Replacement Hip Stem is intended to be implanted to replace a damaged hip joint having large defects in the calcar region as a result of trauma or degenerative disease and in cases where a previous hip replacement component has failed.

This device is a single use implant intended for cemented application.

Device Description: The device is composed of a metallic femoral stem which is designed to articulate with a commercially available acetabular component. The device limits translation and rotation via the geometry of the articulating surface. There is no linkage across the joint.

Proximally, the stem is designed to replace the proximal portion of the femur in cases of severe bone loss. The medial portion is built up to compensate for bone deficiencies. It is further enhanced by a keel, which allows transfer of the proximal load to the calcar region, and resists torsional forces.

There are suture holes in the lateral flange of the proximal platform for reattaching and securing the greater trochanter in cases where a trochanter osteotomy has been performed.

The platform inside the collar is bead blasted; the stem outside the collar distally has a highly polished surface with a mirror-like appearance (according to Biomet's Color Buff Finish spec Q00999). This surface finish allows for some subsidence of the stem within the cement mantle and decrease the incidence of stem loosening.

A proximal to distal taper of the femoral stem parallels the shape of the femur to follow the natural contours of the canal. The tapered geometry loads the cement mantle in compression and promotes evenly distributed stress off-loading. The employment of a PMMA distal stem positioner centralizes the stem within the canal.

The femoral component utilizes a modular head which is taper-fit onto the stem at the time of surgery. The modular heads are manufactured from wrought cobalt-chrome-molybdenum conforming to ASTM F-1537. The stem trunions are identical to Biomet's Type I Tapers for the Zirconia Ceramic Heads cleared in 510(k) K905687. There is a 4 degree included angle on the trunion.

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	Dislocation
Tissue growth failure	

Substantial Equivalence: In function and overall design Biomet's Bi-Metric CoCr Head/Neck Color Buff Replacement Hip Stem Prosthesis is equivalent to other commercially available hip prosthesis currently on the market. These devices include:

HNR (Howmedica)
Solution (DePuy)
Modular Calcar (Zimmer)
Bi-Metric CoCr Head Neck Replacement – Grit Blast Finish (Biomet)

Component Listing

Item #	Description

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1998

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

Re: K983710
Trade Name: 150mm CoCr BiMetric Head/Neck Replacement Hip Stem - Color Buff Finish
Regulatory Class: II
Product Codes: JDI and LZO
Dated: October 19, 1998
Received: October 21, 1998

Dear Mr. McClure:

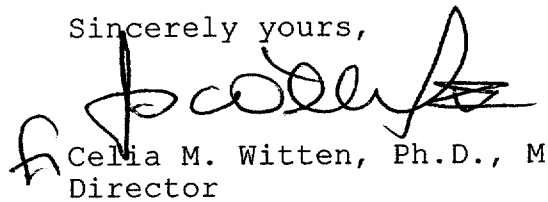
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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) : K983710

Device Name: 150mm CoCr BiMetric Head/Neck Replacement Hip Stem – Color Buff Finish

Indications For Use: Biomet's 150mm CoCr BiMetric Head/Neck Replacement Hip Stem – Color Buff Finish Prosthesis is indicated for use in noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

This device is a single use implant intended for cemented application only.

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983710