

K992058

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 4681-0587

Contact Person: Mary L. Verstynen

Product Code: 87JDI

Device Name: Bi-Metric CoCr Head/Neck Replacement Hip Stems

INTENDED USE: The Bi-Metric CoCr Head/Neck Replacement Hip Stem is intended for use in cases with a diagnoses of:

- a) Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis
- b) Rheumatoid arthritis
- c) Correction of functional deformities
- d) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
- e) Revisions of hip replacement components

The Bi-Metric CoCr Head/Neck Replacement Hip Stem is intended for cemented application and is a single use device.

DEVICE DESCRIPTION: The Bi-Metric CoCr Head/Neck Replacement Hip Stem is a cobalt alloy (Co-Cr-Mo) femoral stem which is designed to articulate with a commercially available acetabular component. It has 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 is "grit blasted" for a roughened surface (200 micro inches) providing for an improved fixation between the stem/cement interface.

There are three resection levels: 34mm, 45mm, and 55mm with four diameters: 9mm, 11mm, 13, and 15mm. The stems are available in 150mm, 200mm, and 250mm lengths. The 150 and 200mm stems are straight and the 250mm stems are bowed right and left specific.

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POTENTIAL RISKS: The potential risks associated with this device are the same as with any joint replacement. These include, but are limited to:

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

SUBSTANTIAL EQUIVALENCE: The Bi-Metric CoCr Head/Neck Replacement Hip Stem is substantially equivalent to the following predicate device in terms of indications, intended use, design, and material.

Predicate device: Bi-Metric CoCr Head/Neck Replacement Hip Stem, K955350

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 1999

Ms. Mary L. Verstynen
Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K992058
Trade Name: Bi-Metric CoCr Head/Neck Replacement System
Regulatory Class: II
Product Code: JDI
Dated: June 15, 1999
Received: June 18, 1999

Dear Ms. Verstynen:

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 (Pre-market 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.

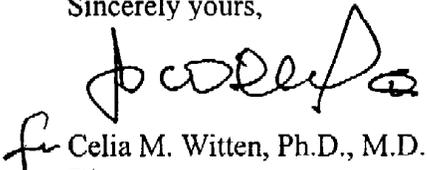
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (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,



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

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510(k) NUMBER (IF KNOWN): K992058

DEVICE NAME: Bi-Metric CoCr Head/Neck Replacement Hip Stem

INDICATIONS FOR USE:

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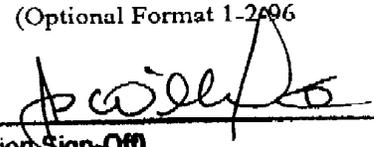
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(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use
(Per 21 CFR 801.109)

OR

Over- The- Counter-
(Optional Format 1-2006)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992058

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