

JUN 28 1999

K991987

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Device: Color Buffed Answer Cemented Femorals

Classification Name: Hip joint metal/polymer semi-constrained cemented prosthesis (CFR 888.3350).

Device Description: The Color Buffed Answer Cemented Femorals are designed to replace a diseased or damaged femoral neck. A modular head attaches to a trunion to complete the femoral side of a total hip. The stems indicated for cement use and are distally tapered to provide better stress distribution through the cement mantel. A proximal, lateral flare insures proximal canal filling and a closer match to normal anatomy. A medial collar provides initial stability and prevents components subsidence. Each stem is straight, thus eliminating the need for a left and right configurations. The stems utilize a modular head to provide an articulating surface with any commercially available acetabular component. These components are intended for use with bone cement, and as such, have PMMA spacers added to the stem to enhance stability within the cement mantel.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but not limited to:

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular diseases	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/Migration	Fracture of the components	Excessive wear
Tissue growth failure	Nerve damage	

A modification was made to the Answer Femoral Components to produce the Color Buffed Answer Cemented Femorals.

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JUN 28 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Dalene Hufziger Binkley
Regulatory Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K991987
Trade Name: Color Buffed Answer Cemented Femoral
Regulatory Class: II
Product Code: JDI
Dated: June 11, 1999
Received: June 14, 1999

Dear Ms. Binkley:

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.

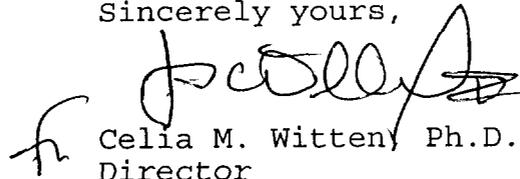
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 ❖ Ms. Dalene H. Binkley

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 at (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): K991987

DEVICE NAME: Color Buffed Answer Cemented Femoral

INDICATIONS FOR USE:

The indications for use for Biomet hip replacement prosthesis include: 1) noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) rheumatoid arthritis; 3) correction of functional deformity; 4) treatment of non-union, femoral neck fracture, and throchanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; 5) revisions of hip replacement components.

Standard surgical and rehabilitative procedures are indicted with this device.

This device is 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
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991987

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