2/11/99

K984154

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Device: APF Porous Coated Line Extension

Classification Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis (888.3358) and hip joint metal/ceramic/ polymer semi-constrained porous coated cemented prosthesis (888.3350).

Intended Use: Biomet's APF Porous Coated Line Extension Prosthesis is intended for use in reconstruction of the hip joint due to damage caused by trauma or degenerative disease and in cases where a previous hip replacement component has failed. The device is intended for cemented application for general use and non-cemented application in skeletally mature individuals undergoing primary surgery for rehabilitating hip joints damaged as a result of non-inflammatory degenerative joint disease or any of its composite diagnosis. The device is a single use implant.

Device Description: The device is composed of a metallic femoral stem (forged titanium) which is designed to articulate with a commercially available acetabular component.

The APF Porous Coated Line Extension stem geometry is designed for proximal, as well as, distal stability and gradual offloading into the bone along the canal. The proximal portion of the stem incorporates a bi-planar taper to encourage proximal offloading, thus reducing stress shielding. This broad proximal geometry fills a greater portion of the metaphysis, thus providing improved rotational stability. In a cemented application, the increased proximal stress transfer of titanium helps preserve the calcar bone and maintain the integrity of the proximal cement mantle.

The stem has a porous coated collar which is incorporated to provide the component stability and stress transfer. Only the underside of the collar is porous coated to help ensure collar-calcar contact and stress distribution. This also provides additional rotational stability and load transfer.

Distally the stem is cylindrical with an anterior bow for left and right configurations. The distal anterior bow more closely matches the anatomic femur to provide rotational stability. This cylindrical design will also enhance implant stability by providing a potential area of biological fixation in situations of proximal bone deficiencies. The lower modulus of elasticity of a titanium stem will also produce less distal stress off-loading and is less likely to fracture the cement mantle.

The APF Porous Coated Line Extension stems will be 75%-100% porous coated to provide maximum proximal and distal fixation through tissue ingrowth in non-cemented

applications or cement adherence in cemented applications. This circumferential closed-pore porous coating potentially seals the the femur from debris migration. Porous coating on the underside of the collar along with extended proximal to distal porous coating, provide areas of potential tissue ingrowth in crucial regions of cortical bone. The roughened surface of the porous coating will also enhance the hip stem/cement bonding, thus improving the chances of long term success. The portion of the stem that is not porous coated (on the 75% and 80% porous coated components) has a 30 grit corse blast finish or (on the 100% porous coated components) the distal tip of the component has a bead blast finish.

The femoral component utilizes a modular head which is taper-fit onto the stem at the time of surgery (Exhibit I). The modular heads are manufactured from wrought cobalt-chromium-molybdenum conforming to ASTM F-1537. The use of mixed metals in surgery is also addressed in MAF-153 (7/10/92 amendment, pg. 54-105). The stem trunions are identical to Biomet's Type I tapers for the Zirconia Ceramic Heads cleared in 510(k) K905687, K913420, and K925345. There is a 4 degree included angle on the trunion. Refer to Exhibit I for a complete listing of modular heads to be used with this stem. For more information on these modular heads, refer to MAF-442.

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 the APF Porous Coated Line Extension is equivalent to other commercially available hip stems currently on the market. These devices include:

Porous APF (Biomet, Inc. – 510(k) K852585)
Integral Hip Stem (Biomet, Inc. – 510(k) K921225)
Reach Femoral Stem (Biomet, Inc. – 510(k) K971824)
AML (DePuy – 510(k) K964650)
The Solution System (DePuy – 510(k) K941942)

Information on these predicate devices and a table providing comparison is contained in Exhibit IV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 1999

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

Re: K984154
Trade Name: APF Porous Coated Line Extension
Regulatory Class: II
Product Codes: LPH and JDI
Dated: November 17, 1998
Received: November 19, 1998

Dear Mr. McClure:

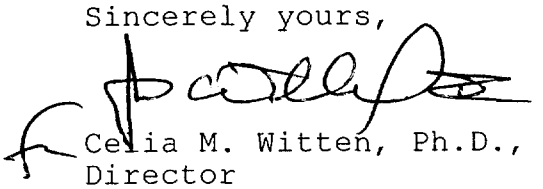
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) : K984154

Device Name: APF Porous Coated Line Extension

Indications For Use: Biomet's APF Porous Coated Line Extension Prosthesis is intended for use in reconstruction of the hip joint due to damage caused by trauma or degenerative disease and in cases where a previous hip replacement component has failed. The device is intended for cemented application for general use and non-cemented application in skeletally mature individuals undergoing primary surgery for rehabilitating hip joints damaged as a result of non-inflammatory degenerative joint disease or any of its composite diagnosis. The device is a single use implant.

Prescription Use Yes Over The Counter Use No

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984154

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