K971824

SUMMARY OF SAFETY AND EFFECTIVENESS

DEC - 4 1997

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

Device: Reach Femoral Hip Component

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: The Reach Femoral Component 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 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.

This 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 Reach stem geometry is designed for proximal, as well as, distal stability and gradual offloading into the bone along the canal. The proximal 100mm of each 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 duckbill porous coated collar which is incorporated to provide component stability and stress transfer. The underside of the collar is porous coated to help ensure collar-calcar contact and stress distribution. This helps to provide rotational stability and load transfer.

Distally, the stem is cylindrical after 100mm with an anterior bow for left and right specific applications. 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 offloading and is less likely to fracture the cement mantle.

The Reach femoral stems will be fully coated to provide maximum proximal and distal fixation through bony ingrowth. This circumferential closed-pore porous coating potentially seals 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 distal tip of the stem is a sisal buff or polished finish, to prevent distal offloading and fixation of the tip (otherwise known as the "pedestal effect").

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
Tissue growth failure	Dislocation
Delayed wound healing	Metal sensitivity
Fracture of the cement	Breakdown of porous surface

Substantial Equivalence: The Reach Femoral Hip Component is substantially equivalent to almost all femoral devices on the market in overall design and intended function. Predicate devices include:

AML® (Depuy, Warsaw, IN) PMA# P820024000

The Solution System® (Depuy, Warsaw, IN) -510(k)# K933942
-510(k)# K941942
-510(k)# K953703

Integral® Total Hip System (Biomet, Inc., Warsaw, IN) -510(k) K921255

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Deborah M. Matarazzo, R.N., B.S.N.
Clinical Research Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

DEC - 4 1997

Re: K971824
Trade Name: Reach Femoral Hip Component
Regulatory Class: II
Product Codes: LZO and LPH
Dated: September 5, 1997
Received: September 8, 1997

Dear Ms. Matarazzo:

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 and the following limitation that the package insert must reflect that the Zirconia Ceramic Femoral Heads are to be used only with forged Ti6Al4V alloy hip stems with the Type I taper trunnions.

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.

Under Section 522(a) of the act, manufacturers of certain types of devices identified by the Act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under Section 522(a)(1)(C) the device cleared for marketing by this letter as requiring postmarket surveillance. The rationale for this decision is contained in the enclosed attachment.

Within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you are required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is attached.

Submit five (5) copies to:

Center for Devices and Radiological Health
Postmarket Surveillance Studies Document Center
Room 3083 (HFZ-544)
1350 Piccard Drive
Rockville, Maryland 20850

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. You should not begin your postmarket surveillance study of this device until the protocol has been approved. Data generated under an unapproved protocol may not satisfy your obligation under section 522. Please note that you must continue to collect and report data needed to maintain compliance with Medical Device Reporting regulations (21 CFR 803).

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete an FDA approved postmarket surveillance study consistent with the protocol will be considered violations of section 522. In accordance with the Medical Device Amendments of 1992, failure

of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the Act (21 U.S.C. 331 (q)(1)(C). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties.

If you have questions concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

for 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

K971824

SUMMARY OF SAFETY AND EFFECTIVENESS

DEC - 4 1997

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

Device: Reach Femoral Hip Component

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: The Reach Femoral Component 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 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.

This 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 Reach stem geometry is designed for proximal, as well as, distal stability and gradual offloading into the bone along the canal. The proximal 100mm of each 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.

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The Reach femoral stems will be fully coated to provide maximum proximal and distal fixation through bony ingrowth. This circumferential closed-pore porous coating potentially seals 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 distal tip of the stem is a sisal buff or polished finish, to prevent distal offloading and fixation of the tip (otherwise known as the "pedestal effect").

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:

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-510(k)# K953703

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Sincerely yours,

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Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971824

Device Name: Reach Femoral Component

Indications For Use:

The Reach Femoral Component is intended for use in reconstruction of the hip joint due to damage caused by trauma or degenerative disease and in cases where previous hip replacement component 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. Use with a Biomet Ceramic Modular Head component or Metallic Modular Head component with appropriate matching Type I Taper.

(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)

OR Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971824