

AUG 24 1998

K982367

SUMMARY OF SAFETY AND EFFECTIVENESS

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.

INTENDED USE: The Reach Femoral Component is indicated for use in:

- a. non-inflammatory degenerative joint disease
- b. osteoarthritis
- c. avascular necrosis
- d. rheumatoid arthritis
- e. revisions procedures where other devices or treatments have failed
- f. correction of functional deformities
- g. treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur with head involvement.

The Reach Femoral Stems are intended for press-fit application and for single use implants.

DEVICE DESCRIPTION: The device is composed of a metallic femoral stem (forged titanium) which is designed to articulate with any Biomet's acetabular component.

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

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-clacar contact and stress distribution. This helps to provide rotational stability and load transfer.

Distally, the stem is cylindrical with an anterior bow for left and right specific applications. The distal anterior bow more closely matches the anatomic femur to provide rotational stability. The cylindrical design will also enhance implant stability

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by providing a potential area of biological fixation in situations of proximal bone deficiencies.

The Reach femoral stems will be fully coated to provide maximum proximal and distal fixation through potential bony ingrowth. This circumferential closed-pore porous coating potentially seals the femur from debris migration. Porous coating in 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 polished finish, to prevent distal off loading 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 not limited to:

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

SUBSTANTIAL EQUIVALENCE: The Reach Femoral Hip Component is substantially equivalent to most femoral devices on the market in overall design and intended function. Predicate devices include:

The Solution System® Depuy, Warsaw, IN 510(k) # K933942, K941942, K953703
Integral® Total Hip system, Biomet, Inc., Warsaw, IN 510(K) #K921255
Foundation® Porous Hip Stem, Encore Orthopedics, Austin TX 510(K) 973302

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Julie K. Ryan
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K982367
Reach Femoral Hip Component
Regulatory Class: II
Product Codes: LPH and LZ0
Dated: July 6, 1998
Received: July 7, 1998

Dear Ms. Ryan:

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,



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

510(k) NUMBER (IF KNOWN): K982367

DEVICE NAME: Reach femoral Component

INDICATIONS FOR USE:

The indications for use of the Reach Femoral Component are:

- a.) non-inflammatory degenerative disease
- b.) osteoarthritis
- c.) avascular necrosis
- d.) rheumatoid arthritis
- e.) revisions of hip replacement components
- f.) treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement.

The Reach stem is intended for press-fit application and for single use implantation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 982367

Prescription Use OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

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