MAY 27 2005 K050251 p 1/2

510(k) Summary

Applicant/Sponsor:

Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person:

Gary Baker
Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639
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Proprietary Name: Balance® Hip System

Common Name: Femoral Hip Stems

Classification Name: The Balance® Hip System femoral stems and compatible shells, heads, and liners included in this submission have the following classifications:

1. Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR §888.3310)
2. Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21 CFR §888.3320)
3. Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR §888.3330)
4. Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR §888.3350)
5. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)
6. Hip joint metal/polymer/metal semi-constrained, porous-coated, uncemented prosthesis (21 CFR §888.3358)

K050251 2/2

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Mallory – Head® Total Hip System – Biomet Inc. (K921181, K030055)
Mayo® Conservative Hip Prosthesis – Zimmer Inc. (K943230)
Bi-Metric® Total Hip System – Biomet Inc. (K921224, K030055)

Device Description: The Balance® Hip System Femoral stems are collarless, porous coated stems available in both standard and Microplasty® stem lengths. The proximal geometry of the Balance® Hip System Femoral stems is designed to promote proximal filling of the metaphysis and provide immediate three point (anterior-proximal, inferior-medial, and distal-lateral) fixation.
The top of the stems have a threaded hole to accommodate the inserter / extractor tool.

Indications for Use: Balance® Hip System Standard Femoral stems

1. Non-inflammatory 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 trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

The Balance® Hip System Standard Femoral stems are intended for uncemented use only.

Indications for Use: Balance® Hip System Microplasty® stems

1. Non-inflammatory 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 trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed femoral head resurfacing component.

The Balance® Hip System Microplasty® stems are intended for uncemented use only.

Summary of Technologies: The Balance® Hip System stems are made of the same materials and utilize the same manufacturing, packaging and sterilization processes as the predicates. Testing determined that the stems are substantially equivalent to the predicate stems.

Non-Clinical Testing: Reference literature and performance data demonstrate that the Balance® Hip System stems are substantially equivalent to the predicate femoral hip stems.

All trademarks are property of Biomet, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Mr. Gary Baker
Regulatory Specialist
Biomet Incorporated
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K050251
Trade/Device Name: Balance® Hip System Microplasty® Stems
Regulation Number: 21 CFR 888.3310, 888.3320, 888.3330, 888.3350, 888.3358
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis; Hip joint metal/metal semi constrained, with a cemented acetabular component, prosthesis; Hip joint metal/ polymer semi-constrained cemented prosthesis; Hip joint metal/polymer/metal semi-constrained porous-coated, uncemented prosthesis
Regulatory Class: III
Product Code: KWZ, JDL, KWA, JDI, LZO, MEH, LPH, LZY, KWY
Dated: May 6, 2005
Received: May 9, 2005

Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (IF KNOWN): K050251

Device Name: Balance® Hip System Standard Femoral Stems

Indications for Use:

1. Non-inflammatory 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 trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

Balance® Hip System Femoral Stems are intended for uncemented use only.

Specific indications for compatible components that can be used with the above femoral stems include:

Constrained Liners (K030047)

Constrained liners are intended for general use in skeletally mature individuals undergoing primary and/or revision surgery at high risk of hip dislocation due to history of prior dislocation, joint or bone loss, soft [tissue] laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

OSS / Salvage Systems / Total Femur (K974558, K002757, K021380, K033871)

Salvage/Oncology Hip and Total Femur components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrodesis.

Interlocking Stems (K990830, K042774)

Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis.

Prescription Use ___X___ AND/OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Sign-Off)

...ion of General, Restorative, Neurological Devices

...Number K050251

Indications For Use

510(k) Number (IF KNOWN): K050251

Device Name: Balance® Hip System Microplasty® Stems

Indications for Use:

1. Non-inflammatory 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 trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed femoral head resurfacing components.

Balance® Hip System Microplasty® Stems are intended for uncemented use only.

Specific indications for compatible components that can be used with the above femoral stems include:

Constrained Liners (K030047)

Constrained liners are intended for general use in skeletally mature individuals undergoing primary and/or revision surgery at high risk of hip dislocation due to history of prior dislocation, joint or bone loss, soft [tissue] laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

OSS / Salvage Systems / Total Femur (K974558, K002757, K021380, K033871)

Salvage/Oncology Hip and Total Femur components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrodesis.

Interlocking Stems (K990830, K042774)

Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis.

Prescription Use ___X___ AND/OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050251