AUG 1 1 2003

K030055

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BIOMET

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name(s): Mallory/Head® Total Hip System, HA Mallory/Head® Total Hip System, Bi-Metric® Femoral Components, HA Bi-Metric® Femoral Component, Taperloc® Femoral Component, HA Taperloc® Femoral Component, Integral® Femoral Component, Modular Hip Stems, HA Modular Reach®, APF Femoral Component, PMI® Femoral Component, Universal® Acetabular Component, Index® Acetabular Component, A-B (Precept®) Acetabular Component, Pegged Acetabular Component, Flanged Acetabular Component

Common or Usual Name: Total Hip Prostheses

Classification Name: Prosthesis, hip, semi-constrained, metal/polymer, porous coated uncemented (21 CFR 888.3358)

Device Product Code(s): LPH, LZO, MEH

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Lateralized Integral® Femoral Component – K984296
130° Integral® Femoral Component – K984408
Fenning (Osteocap RS®) Femoral Component – K960303
Reach® Femoral Component – K982367, K000760

Device Description: All devices are metallic, tapered hip femoral components. Each utilizes a modular femoral head component that is taper fit onto the stem at the time of surgery.

Intended Use: Non-cemented total hip replacement

Summary of Technologies: The devices to be covered by this 510(k) for expanded indications are geometrically identical to devices previously covered by 510(k).

Clinical and Non-Clinical Testing: None provided

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2003

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K030055
Trade/Device Name: Expanded Indications for Non-Cemented Porous Coated Total Hip Prostheses
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH and MEH
Dated: May 22, 2003
Received: May 23, 2003

Dear Ms. Beres:

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 (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030055

Device Name: Expanded Indications for Non-Cemented Porous Coated Total Hip Prostheses

Indications For Use:

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) Revision of previously failed total hip arthoplasty.

Alan Witt

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

510(k) Number K030055

(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 No

(Optional Format 1-2-96)