AUG 21 2003

K032396

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BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Orthopedics, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Gary Baker
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587
Telephone: (574) 267-6639 Ext. 1568
Fax: (574) 372-1683

Proprietary Name: RingLoc® 36mm Liners and Modular Femoral Heads

Common Name: Acetabular liners and femoral heads.

Classification Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis (21 CFR §888.3358), and hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR §888.3350).

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: RingLoc® 32mm Liners cleared in 510(k) K970501, and 32mm Modular Femoral Heads cleared in 510(k) K974558.

Device Description:

The RingLoc® 36mm Liners are manufactured from ArCom® processed ultra-high molecular weight polyethylene (UHMWPE) conforming to ASTM F648. The Modular Femoral Heads are manufactured from wrought Co-Cr-Mo conforming to ASTM F1537. They incorporate the standard Biomet Type I taper and come in neck sizes –6mm, -3mm, STD, +3mm, +6mm, +9mm, and +12mm. The +9mm and +12mm heads incorporate a skirt to maintain the same point of rotation.

Intended Use:

The RingLoc® 36mm Liners and Modular Femoral Heads are intended for either cemented of uncemented use.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639 ■ FAX 574.267.8137 ■ E-MAIL biomet@biomet.com

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Summary of Technologies:

The RingLoc® 36mm Liners and Modular Femoral Heads are manufactured from the same materials, utilizing the same manufacturing practices, and conforming to the same standards as the predicate devices.

Non-Clinical Testing:

Mechanical testing and published literature determined that 36mm liners and heads presented no new unacceptable risks, and are therefore, substantially equivalent to the predicate devices.

Clinical Testing:

No clinical testing was necessary for determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2003

Mr. Gary Baker
Regulatory Specialist
Biomet Orthopedics, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K032396
Trade/Device Name: RingLoc® 36mm Liners and Modular Femoral Heads
Regulation Numbers: 21 CFR 888.3350, 21 CFR 888.3358
Regulation Names: Hip joint metal/polymer semi-constrained cemented prosthesis, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Codes: JDI, LPH
Dated: August 1, 2003
Received: August 4, 2003

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.

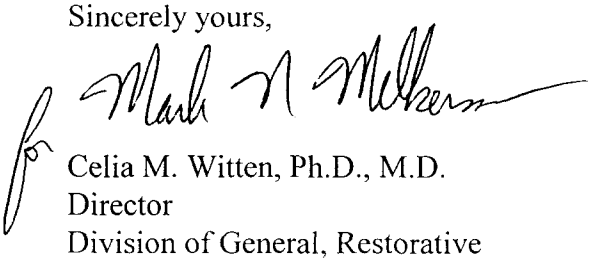
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 (301) 594-4659. 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/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

Statement of Indications For Use

510(k) Number (IF KNOWN): K032396

Device Name: RingLoc® 36mm Liners and Modular Femoral Heads

Indications for Use:

The indications for use of the Biomet hip replacement prosthesis include:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of nonunion, 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.

These devices are intended for either cemented or uncemented use.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K032396

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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