SEP 2 9 2005

K051569

BIOMET

## 510(k) Summary

**Applicant/Sponsor:** Biomet Manufacturing Corp.

**Contact Person:** Patricia Sandborn Beres
Senior Regulatory Specialist

**Proprietary Name:** RingLoc® Bi-Polar Acetabular Component

**Common Name:** Bi-Polar Acetabular Component

**Classification Name:** Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390)

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:** Biomet Bipolar Prosthesis (K833175), and Biomet TriPolar System (K991990)

**Device Description:** The Bi-Polar device consists of a large outer shell with a polyethylene insert that captures a modular head component of a femoral hip stem. The outer surface of the shell is highly polished in order to articulate with the natural acetabular bone. Outer diameters of 41mm to 70mm allow the surgeon to fill the acetabular cavity. Inserts accept two size modular heads, 22mm and 28mm. The insert is held in place by a thin metal ring that is pre-assembled into the shell which snaps into a groove in the insert.

**Intended 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 trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

**Summary of Technologies:** The technological characteristics (materials, design, sizing, and indications) of the RingLoc® Bi-Polar Acetabular Components are similar to or identical to the predicate devices.

**Non-Clinical Testing:** Mechanical testing of the assembly and disassembly forces was conducted.

**Clinical Testing:** None provided





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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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SEP 29 2005

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
56 East Bell Drive, P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K051569
Trade/Device Name: RingLoc® Bi-Polar Acetabular Component
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY, JDI, LPH, LZO, MEH
Dated: September 21, 2005
Received: September 22, 2005

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 (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/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
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): K051569

Device Name: RingLoc® Bi-Polar Acetabular Component

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 trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

Mark A Miller

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

510(k) Number K051569

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)