

NOV - 9 2004



K042029

510(k) Summary

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

**Contact Person:** Patricia Sandborn Beres  
Senior Regulatory Specialist  
Phone: (574) 267-6639

**Proprietary Name:** X-Series Integral® RPP Hip Femoral Components

**Common Name:** Hip replacement prosthesis

**Classification Name:** Prosthesis, hip, semi-constrained, metal/polymer, porous coated uncemented (21 CFR 888.3558)

**Legally Marketed Device to which Substantial Equivalence is Claimed:** X-Series Integral® Hip Femoral Component (K030501)

**Device Description:** The X-Series Integral® RPP Femoral Components are identical to the predicate X-Series Integral® Femoral components in overall design. The X-Series Integral® RPP Femoral Components have a reduced proximal geometry. Both device series are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F-136.

**Indications for Use:** Non-cemented total joint replacement in cases of:

- 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 by other techniques.
- 5) Revision of previously failed total hip arthroplasty

**Summary of Technologies:** The technological characteristics (materials, design, sizing and indications) of the X-Series Integral® femoral components are similar to or identical to the predicate device.

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P.O. Box 587  
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56 E. Bell Drive  
Warsaw, IN 46582

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574.267.6639

FAX  
574.267.8137

E-MAIL  
biomet@biomet.com

**Non-Clinical Testing:** Finite Element Analysis and engineering analysis were conducted to insure the design changes would not effect the safety of the device.

**Clinical Testing:** None provided



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K042029

Trade/Device Name: X-Series Integral<sup>®</sup> Reduced Proximal Profile (RPP) Femoral  
Components

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prostheses.

Regulatory Class: II

Product Code: LPH

Dated: October 11, 2004

Received: October 12, 2004

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.

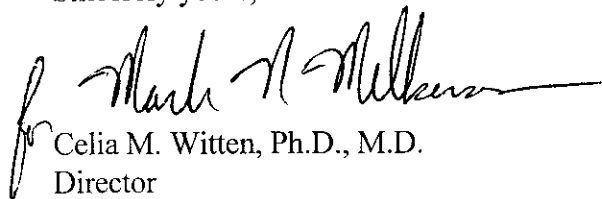
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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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) 276-0120. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

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

# Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: X-Series Integral® RPP Femoral Components

## Indications For Use:

Non-cemented total joint replacement in cases of:

- 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 by other techniques.
- 5) Revision of previously failed total hip arthroplasty

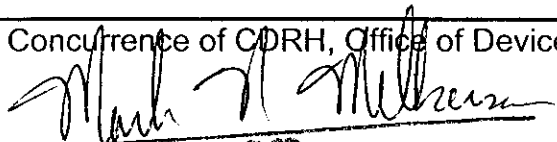
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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)

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

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K042029 *MNR*

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