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BIOMET
ORTHOPEDICS, INC.

510(k) Summary

DEC 0 8 2006

Preparation Date: September 28, 2006

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

Contact Person: Becky Earl

Proprietary Name: ArComXL™ Polyethylene Liners and 38/40mm Femoral Heads

Common Name: UHMWPE; Femoral Heads

Classification Name:
- hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis (888.3358)
- hip joint metal/polymer semi-constrained cemented prosthesis (888.3350)
- hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (888.3353)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: ArComXL™ Acetabular Liners— K042051 (Biomet, Inc.), ArCom® Acetabular Liners—K023357 (Biomet, Inc.), 36mm MaxRom™ Acetabular Liners—K032396 (Biomet, Inc.), M2a™ Acetabular System—K011110 (Biomet, Inc.), and M2a Magnum™ System—K042037 (Biomet, Inc.)

Device Description: Biomet Manufacturing Corp. is adding additional sizes and designs to the predicate ArComXL™ Acetabular Liners (K042051). The same manufacturing process used in the predicate results in a higher cross-linked polyethylene that Biomet will herein refer to as ArComXL™. The femoral heads, sizes 38mm and 40mm, are a one-piece design with neck length variations ranging from –6mm to +9mm made from CoCrMo.

Intended 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.

Cemented and Uncemented Applications

Summary of Technologies: The intended use, indications, contraindications, and design specifications of the acetabular liners remain similar or identical to their predicate component counterparts. The only exception is the addition of 32 and 36mm in two designs and 38 and 40mm size liners for all included designs. The raw material being utilized in the manufacture of the subject devices is an ultra-high

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ArComXL™ Polyethylene Liners and 38/40mm Femoral Heads (Continued)

molecular weight polyethylene (UHMWPE) per ASTM F-648, identical to the predicate (K042051). The manufacturing and sterilization methods for ArComXL™ (UHMWPE) Acetabular Liners were previously established in K042051.

The intended use, indications, contraindications, and design specifications of the femoral heads are identical to their predicates with the exception of the articulating surface which is changed from metal-on-metal to metal-on-polyethylene and may be used in either cemented or uncemented applications.

Non-Clinical Testing: Verification activities were performed on ArComXL™ liners, which met or exceeded current standards or guidelines.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2006

Biomet Manufacturing Corp.
% Ms. Becky Earl
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K062997
Trade/Device Name: ArComXL™ Polyethylene Liners and 38/40mm Femoral Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: September 29, 2006
Received: October 02, 2006

Dear Ms. Earl:

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.

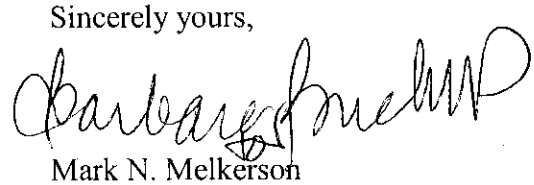
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: ArComXL™ Polyethylene Liners and 38/40mm Femoral Heads

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.

Cemented and Uncemented Applications

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(Part 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 K062997