K042051

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BIOMET

510(k) Summary

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

Contact Person: Tracy Bickel Johnson, RAC

Proprietary Name: ArComXL™ Polyethylene Liners

Common Name: UHMWPE

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)

Substantially Equivalent Devices: -ArCom® Polyethylene Liners and Components (K023357)
-RingLoc® 36mm Liners (K032396)

Device Description: Biomet Manufacturing Corp. is modifying the manufacturing process of UHMWPE used in the fabrication of polyethylene acetabular components. The modified manufacturing process results in a higher cross-linked polyethylene, that Biomet will herein refer to as ArComXL™.

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 nonunion, femoral neck 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 subject components remain identical to their predicate component counterparts. The raw material being utilized in the manufacture of both the subject and the predicate devices remains a ultra-high molecular weight polyethylene (UHMWPE) per ASTM F-648. The modifications to the manufacturing process of this polyethylene will be introduced in order to create a higher cross-linked polyethylene. The safety and effectiveness of this cross-linked polyethylene in acetabular applications, as well as the proposed wear claims, are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

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510(k) Summary- Page 2 of 3
ArComXL™ Polyethylene Liners

Claims:

Hip Simulator Wear
The Biomet ArComXL™ polyethylene acetabular inserts (Part No.: XL-105933) tested are isostatically compression molded highly crosslinked components (50kGy gamma irradiated under argon) that are sterilized in air by either gas plasma or ethylene oxide. ArComXL™ was compared to identical predicate polyethylene liners (Part No.: 12-105893) that were machined from isostatically molded polyethylene that was subsequently gamma sterilized (25-40kGy) in argon. A side by side hip simulator wear test of the two materials showed a 47% reduction in the volumetric wear rate (34.9 opposed to 65.8 $mm^3/10^6$ cycles) for ArComXL™ (EtO sterilized) when compared to the predicate device. All inserts in this study mate with either a 50 or 52mm acetabular shell, have a standard rim, a 32 mm inner diameter, and a 4.75 mm bearing thickness. Testing was performed under multiaxial hip joint simulation for five (5) million cycles, using a Paul Hip load profile with a maximum load of 2.4kN, 32 mm CoCr articulating heads, and a bovine calf serum lubricant. The results of *in vitro* hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

Abrasive Hip Simulator Wear
The Biomet ArComXL™ polyethylene acetabular inserts (Part No.: XL-105933) tested are isostatically compression molded highly crosslinked components (50kGy gamma irradiated under argon) that are sterilized in air by either gas plasma or ethylene oxide. ArComXL™ was compared to identical predicate polyethylene liners (Part No.: 12-105893) that were machined from isostatically molded polyethylene that was subsequently gamma sterilized (25-40kGy) in argon. After 5 million cycles of hip simulator wear with no additives, bone cement particulate was added to simulate abrasive conditions for two (2) million cycles. Under abrasive conditions, the Biomet ArComXL™ (EtO sterilized) polyethylene acetabular insert (Part No.: XL-105933) showed a 64% reduction in volumetric wear rate (109.8 opposed to 309.0 $mm^3/10^6$ cycles) when compared to the same acetabular inserts fabricated from the predicate polyethylene (Part No.: 12-105893). These inserts mate with either a 50 or 52mm acetabular shell, have a standard rim, a 32mm inner diameter, and a 4.75 mm bearing thickness. Testing was performed under multiaxial hip joint simulation for two (2) million cycles, using a Paul Hip load profile with a maximum load of 2.4kN, 32 mm CoCr articulating heads, and bovine calf serum lubricant. The results of *in vitro* hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

Free Radicals
The Biomet ArComXL™ polyethylene material tested is isostatically compression molded, highly crosslinked (50kGy gamma irradiated under argon), and sterilized in air by either gas plasma or ethylene oxide. ArComXL™ was compared to predicate polyethylene material that was machined from isostatically molded polyethylene that was subsequently gamma sterilized (25-40kGy) in argon. The Biomet ArComXL™ (Gas Plasma sterilized) material, showed a 94% reduction in the number of free radicals ($0.22x10^{15}$ compared to $3.82x10^{15}$ spins/g) versus the predicate polyethylene material. Testing was performed by an independent laboratory using Electron Spin Resonance (ESR). Results of *in vitro* free radical testing have not been shown to quantitatively predict oxidation resistance.

Oxidative Stability
The Biomet ArComXL™ polyethylene material tested is isostatically compression molded, highly crosslinked (50kGy gamma irradiated under argon), and sterilized in air by either gas plasma or ethylene oxide. ArComXL™ was compared to predicate polyethylene material that was machined from isostatically molded polyethylene that was subsequently gamma sterilized (25-40kGy) in argon.

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ArComXL™ Polyethylene Liners

The Biomet ArComXL™ (Gas Plasma sterilized) material did not show any measurable oxidation by FTIR (oxidation index less than 0.4 throughout the sample) after accelerated aging per ASTM F2003-00, which is designed to simulate several years of shelf-aging in air. In contrast, when the predicate material was removed from inert packaging (packaging that was vacuum sealed after purging with argon), it did show measurable levels of oxidation after accelerated aging (oxidation index was greater than 1.1 at a depth of 1 mm). Further, after accelerated aging the average ultimate load for all three ArComXL™ axes (Gas Plasma Sterilized) remained higher than the peak load (31% higher; 91.8N vs. 70.2N); whereas the ultimate load for the isotropic predicate material was significantly less than the peak load (44% lower; 42.6N vs. 75.6N) as measured by small punch testing, ASTM F2183-02.

Mechanical Strength
The Biomet ArComXL™ polyethylene material tested is isostatically compression molded, highly crosslinked (50kGy gamma irradiated under argon), and sterilized in air by either gas plasma or ethylene oxide. ArComXL™ was compared to predicate polyethylene material that was machined from isostatically molded polyethylene that was subsequently gamma sterilized (25-40kGy) in argon. The Biomet ArComXL™ (EtO sterilized) material showed a 30% increase in ultimate tensile strength (from 47 MPa to 61 MPa) in the longitudinal axis versus the predicate polyethylene material. The tensile testing was performed per ASTM standard D638-02a using Type 5 tensile specimens.

Non-Clinical Testing: Verification activities were performed on ArComXL. 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

MAR 8 - 2005

Ms. Tracy Bickel Johnson, RAC
Regulatory Associate
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K042051
Trade Name: ArComXL™ Polyethylene Liners
Regulation Number: 21 CFR 888.3350, 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: JDI, LPH
Dated: December 6, 2004
Received: December 8, 2004

Dear Ms. Johnson:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C Provost

Miriam Provost, Ph.D.
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): K042051

Device Name: ArComXL™ Polyethylene Liners

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.
5) Revision of previously failed total hip arthroplasty.

Cemented and Uncemented Applications

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)

Miriam C Provost

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

510(k) Number K042051

Claim Statements:

Hip Simulator Wear

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