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JUN 29 2005

510(K) SUMMARY

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

Contact Person: Tracy Bickel Johnson, RAC

Proprietary Name: ArComXL™ Acetabular Liners and Biolox® delta Ceramic Heads

Common Name: Acetabular liners and ceramic heads

Classification Name: LZO- hip joint/ceramic/polymer, semi-constrained, cemented or non-cemented prosthesis (888.3353)

Substantially Equivalent Devices: ArComXL™ Acetabular Liners (K042051)
Biolox® delta Ceramic Heads (K042091)

Device Description: The ArComXL™ polyethylene liners are manufactured from highly cross-linked polyethylene conforming to ASTM F648 that was previously cleared in K042051. ArComXL™ is available in three designs: MaxRom, Hi-Wall, and 10°.

Biolox® *delta* Ceramic Heads (K042091) are composed of Transition-Toughened-Platelet-Alumina (TTPA). The highly polished spherical surface articulates with the ArComXL™ polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper.

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.

Intended for cemented and uncemented applications

Summary of Technologies: The design, sizes, intended use, indications, contraindications, and design specifications of the subject components remain identical to their predicate component counterparts. This submission allows the ArComXL™ Acetabular Liners and the Biolox® *delta* Ceramic Heads to be used together.

Non-Clinical Testing: Volumetric wear testing was performed on ArComXL™ Acetabular Liners and the Biolox® delta Ceramic Liners showing less wear.

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

JUN 2 9 2005

Ms.Tracy Bickel Johnson
Manager of Regulatory Affairs
Biomet Incorporated
P.O. Box 587
Warsaw, Indiana 46582

Re: K051411
Trade/Device Name: ArComXL™ Acetabular Liners and Biolox® *delta* Ceramic Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: May 27, 2005
Received: May 31, 2005

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, 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):

Device Name: ArComXL™ Acetabular Liners and Biolox® *delta* Ceramic 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.

Intended for cemented and uncemented applications

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051411