NOV 23 2005

510(k) Summary

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

Contact Person: Allison K. Koskey
Regulatory Specialist

Proprietary Name: ArComXL™ Polyethylene Rx90™ Low Profile Acetabular Liners

Common Name: Acetabular liner

Classification Name(s):

1) Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358)
2) Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 88.3350)
3) Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)
4) Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Rx90™ Low Profile Acetabular System (K042989)

Device Description: The new device is composed of ArComXL™ with inner diameters of 28, 32, and 36mm.

Intended Use: The ArComXL™ Polyethylene Rx90™ Low Profile Acetabular Liners are indicated for single cemented or non-cemented use 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 designs, intended use, contraindications, and design specifications of the subject components remain identical to their predicate counterparts. This submission allows the Rx90™ Low Profile Acetabular System to be composed of ArComXL™ with an inner diameter of 36mm.

Non-Clinical Testing: Verification activities were previously performed on the ArComXL™ polyethylene predicate devices. Testing 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

NOV 23 2005

Ms. Allison K. Koskey
Regulatory Specialist
Biomet Manufacturing Corp.
56 East Bell Drive
P. O. Box 587
Warsaw, Indiana 46582

Re: K052255
ArComXL™ Polyethylene Rx90™ Low Profile Acetabular Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Codes: LPH, LZO, JDI, KWZ, MEH
Dated: October 28, 2005
Received: October 31, 2005

Dear Ms. Koskey:

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.

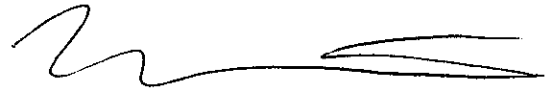
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



for 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): K052255

Device Name: ArComXL™ Polyethylene Rx90™ Low Profile Acetabular Liners

Indications For Use: The ArComXL™ Polyethylene Rx90™ Low Profile Acetabular Liners are indicated for cemented or non-cemented use 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)

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

510(k) Number K052255