K023357

BIOMET

NOV 6 2002

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Contact Person: Tracy J. Bickel
(574) 267-6639

Proprietary Name: ArCom® Polyethylene Liners and Components

Common Name: UHMWPE

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

Substantially Equivalent Devices: Please see the attached page(s) for the specific equivalent devices.

Device Description: Biomet's polyethylene components are manufactured from UHMWPE (GUR 1050) resin conforming to ASTM F-648, ISO 5834-1, and ISO 5834-2. This resin is isostatically compression molded under constant temperature and pressure and formed into acetabular components, which are designed to replace the articulating portion of the hip joint.

Indications for Use: Please see the attached page(s) for the specific indications for use statements.

Summary of Technologies: The UHMWPE resin has been changed from 1900H to GUR 1050. The devices' technological characteristics (materials, design, sizing, and indications) are similar or identical to the predicate device.

Non-Clinical Testing: The following verification activities were performed on GUR 1050 resin: Process Validation (tensile, impact, and physical properties), Hip Simulator, Aging behavior and shelf life. All of which met or exceeded current standards or guidelines; therefore, substantially equivalent to the predicate device.

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

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56 E. Bell Drive
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574.267.6639

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574.267.8137

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biomet@biomet.com

ArCom® Polyethylene Liners and Components

510(k) Number	Device Description	Indications for Use
K920640 K926107	**Ringloc UHMWPE Hi-Wall** 22, 26, 28, and 32 mm **Ringloc UHMWPE 10°** 22, 28, and 32mm	1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis, 2. Rheumatoid arthritis, 3. Correction of functional deformity, 4. Revision procedures where other treatments or devices have failed and 5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. For Cemented use only
K920639	**RX 90 std. Hi-Wall** 28mm **RX 90 +5 Deep** 28mm	
K921274	**Impact Hi-Wall** 28 and 32mm	1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis, 2) Rheumatoid arthritis, 3) Correction of functional deformity, 4) Revision procedures where other treatments or devices have failed and 5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. For Non-Cemented use only
K926107	**Mod. Hi-Wall LNR** 28 and 32mm **Mod. 10° LNR** 28 and 32mm **RX 90 std. Hi-Wall** 28mm **RX 90 +5 Deep** 28mm	1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis, 2. Rheumatoid arthritis, 3. Correction of functional deformity, 4. Revision procedures where other treatments or devices have failed and 5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. For Cemented use only

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ArCom® Polyethylene Liners and Components

510(k) Number	Device Description	Indications for Use
K950761	**Ringloc UHMWPE Hi-Wall** 22, 26, 28, and 32 mm **Ringloc UHMWPE 10°** 22, 28, and 32mm **Ringloc LP Hi-Wall Arcom** 22, 28, and 32mm **Ringloc Arcom LP 10°** 22, 28, and 32mm	1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis, 2. Rheumatoid arthritis, 3. Correction of functional deformity, 4. Revision procedures where other treatments or devices have failed and 5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. For Cemented and Non-cemented use
K954417	**Arcom +5mm**	
K950761 K954417	**Arcom Std. Face** 28and 32mm **Arcom Hi-Wall** 22, 26, 28, and 32mm **Arcom 10°** 22, 26, 28, and 32 mm **Arcom 10° Hi-Wall** 28 and 32mm	
K970501	**Arcom Std. Face** 28 and 32mm **Arcom Hi-Wall** 22, 26, 28, and 32mm **Arcom 10°** 22, 26, 28, and 32 mm **Arcom 10° Hi-Wall** 28 and 32mm **Arcom +5** 28mm	Intended for use in reconstruction of the hip joiint due to disease, deformity of trauma. The device is intended for cemented application for general use and non-cemented application in skeletally mature individuals undergoing primary surgery for rehabilitating hip joints damaged as a result of non-inflammatory degenerative joint disease or any of its composite diagnoses. Single use implant

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 2002

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K023357
Trade/Device Name: ArCom® Polyethylene Liners and Components
Regulation Number: See Enclosed List
Regulation Name: See Enclosed List
Regulatory Class: Class II
Product Code: See Enclosed List
Dated: October 4, 2002
Received: October 7, 2002

Dear Ms. Bickel:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Miriam C. Provost

for 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

Enclosures
(1) Indications for Use Forms (4 pages)
(2) Classification Table (2 pages)

Enclosure 1

K023357

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Product	Product Code	Classification Nomenclature	Class. Code	510(k)
Ringloc UHMWPE Hi-Wall 22, 26, 28, and 32 mm	LPH and JDI	LPH- hip joint metal/polymer semi-constrained porous coated uncemented prosthesis JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3358 888.3350	K950761
Ringloc UHMWPE Hi-Wall 22, 26, 28, and 32 mm	JDI	JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3350	K920640 K926107
Ringloc UHMWPE 10° 22, 28, and 32mm	LPH and JDI	LPH- hip joint metal/polymer semi-constrained porous coated uncemented prosthesis JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3358 888.3350	K950761
Ringloc UHMWPE 10° 22, 28, and 32mm	JDI	JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3350	K920640 K926107
Ringloc LP Hi-Wall Arcom 22, 28, and 32mm	LPH and JDI	LPH- hip joint metal/polymer semi-constrained porous coated uncemented prosthesis JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3358 888.3350	K950761
Ringloc Arcom LP 10° 22, 28, and 32mm	LPH and JDI	LPH- hip joint metal/polymer semi-constrained porous coated uncemented prosthesis JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3358 888.3350	K950761
Arcom Std. Face 28and 32mm	LPH and JDI	LPH- hip joint metal/polymer semi-constrained porous coated uncemented prosthesis JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3358 888.3350	K950761 K970501 K954417
Arcom Hi-Wall 22, 26, 28, and 32mm	LPH and JDI	LPH- hip joint metal/polymer semi-constrained porous coated uncemented prosthesis JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3358 888.3350	K950761 K970501 K954417
Arcom 10° 22, 26, 28, and 32 mm	LPH and JDI	LPH- hip joint metal/polymer semi-constrained porous coated uncemented prosthesis JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3358 888.3350	K950761 K970501 K954417
Arcom 10° Hi-Wall 28 and 32mm	LPH and JDI	LPH- hip joint metal/polymer semi-constrained porous coated uncemented prosthesis JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3358 888.3350	K950761 K970501 K954417

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Product	Product Code	Classification Nomenclature	Class. Code	510(k)
Arcom +5 28mm	LPH and JDI	LPH- hip joint metal/polymer semi-constrained porous coated uncemented prosthesis JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3358 888.3350	K970501 K954417
Mod. Hi-Wall LNR 28 and 32mm	JDI	JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3350	K926107
Mod. 10° LNR 28 and 32mm	JDI	JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3350	K926107
RX 90 std. Hi-Wall 28mm	JDI	JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3350	K920639 K926107
RX 90 +5 Deep 28mm	JDI	JDI- hip joint metal/polymer semi-constrained cemented prosthesis	888.3350	K920639 K926107
Impact Hi-Wall 28 and 32mm	LZO LPH	LZO- prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented LPH- hip joint metal/polymer semi-constrained porous coated uncemented prosthesis	888.3353 888.3358	K921274

510 (k) Number (if known) : K023357

Device Name: Arcom® Polyethylene Liners and Components

Indications for Use: The products found in the original 510(k) K950761, and K954417 will use the following Indications for Use:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
2) Rheumatoid arthritis,
3) Correction of functional deformity,
4) Revision procedures where other treatments or devices have failed and
5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

For Cemented and Non-cemented use

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109)

OR

Over-The-Counter-Use_____ (Optional Format 1-2-96)

510 (k) Number (if known) : K023357

Device Name: Arcom® Polyethylene Liners and Components

Indications for Use: The products found in the original 510(k) K920639, K920640 and K926107 will use the following Indications for Use:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
2) Rheumatoid arthritis,
3) Correction of functional deformity,
4) Revision procedures where other treatments or devices have failed and
5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

For Cemented use only

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023357

510 (k) Number (if known) : K023357

Device Name: Arcom® Polyethylene Liners and Components

Indications for Use: The products found in the original 510(k) K921274 will use the following Indications for Use:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
2) Rheumatoid arthritis,
3) Correction of functional deformity,
4) Revision procedures where other treatments or devices have failed and
5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

For Non-Cemented use only

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number K023357

510 (k) Number (if known) : K023357

Device Name: Arcom® Polyethylene Liners and Components

Indications for Use: The products found in the original 510(k) K970501 will use the following Indications for Use:

Intended for use in reconstruction of the hip joint due to disease, deformity of trauma. The device is intended for cemented application for general use and non-cemented application in skeletally mature individuals undergoing primary surgery for rehabilitating hip joints damaged as a result of non-inflammatory degenerative joint disease or any of its composite diagnoses.

The device is a single use implant

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109)

OR

Over-The-Counter-Use_____ (Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K023357