

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.

All trademarks are property of Biomet, Inc.



JUN 29 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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.

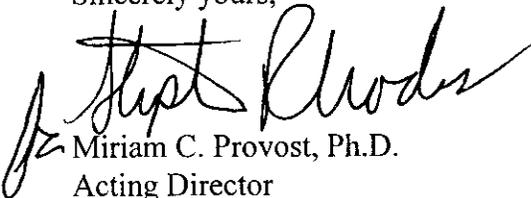
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms.Tracy Bickel Johnson

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
(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 K051411



JUN 29 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tracy Bickel Johnson
Manager of Regulatory Affairs
Biomet Incorporated
P.O. Box 587
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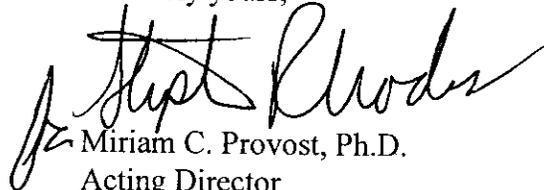
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Page 2 – Ms. Tracy Bickel Johnson

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Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam C. Provost". The signature is written in a cursive style with a large initial "M".

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

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 31, 2005

BIOMET, INC.
56 EAST BELL DR.
P.O. BOX 587
WARSAW, IN 46582
ATTN: TRACY BICKEL JOHNSON

510(k) Number: K051411
Received: 31-MAY-2005
Product: ARCOMXL POLYETHYLENE
LINERS AND BIOLOX
DELTA HEADS

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K05/411

BIOMET
ORTHOPEDICS, INC.

May 27, 2005

Document Mail Center (HFZ-401)
Center for Device and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

100-111111

Reference: "Special" 510(k)
ArComXL™ Polyethylene Liners with BioloX® *delta* Ceramic Heads
Payment ID Number: (b)(4)Trade Secret

Dear Sir or Madam:

Enclosed is a "Special" 510(k): **Device Modification** submission for ArComXL™ Acetabular Liners for use with BioloX® *delta* ceramic heads. The ArComXL™ Acetabular Liners have been previously cleared in K042051, while the BioloX® *delta* Ceramic Heads have previously cleared in K042091. This submission is for the purpose of combining the heads and the liners for use together. We believe this device is substantially equivalent* to cleared devices and warrants a "Special" 510(k).

The sponsor of this 510(k) considers the existence of this notification confidential until a determination of substantial equivalence is made. Permission to fax or e-mail information related to this submission is granted by the Sponsor.

Sincerely,



Tracy Bickel Johnson, RAC
Manager of Regulatory Affairs
Biomet Manufacturing Corp.

510(k) submitted in duplicate

*Any statement made in conjunction with this submission regarding and/or a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, 42 FR 42520 (Docket No. 76N-0355)]

MAILING ADDRESS
P.O. Box 5887
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46583

OFFICE
571.267.6639

FAX
571.267.8137

E-MAIL
biomet@biomet.com

SKB3
OR
4/17

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret Write the Payment Identification number on your check.															
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:																	
<ol style="list-style-type: none"> Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 																	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) BIOMET INC 56 EAST BELL DRIVE P O BOX 587 WARSAW IN 46581-0587 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)		2. CONTACT NAME Tracy Johnson 2.1 E-MAIL ADDRESS tracy.johnson@biometmail.com 2.2 TELEPHONE NUMBER (include Area code) 574-372-1761 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 574-372-1683															
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma) Select an application type: <table border="0"> <tr> <td><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party</td> <td>3.1 Select one of the types below</td> </tr> <tr> <td><input type="checkbox"/> Biologics License Application (BLA)</td> <td><input checked="" type="checkbox"/> Original Application</td> </tr> <tr> <td><input type="checkbox"/> Premarket Approval Application (PMA)</td> <td>Supplement Types:</td> </tr> <tr> <td><input type="checkbox"/> Modular PMA</td> <td><input type="checkbox"/> Efficacy (BLA)</td> </tr> <tr> <td><input type="checkbox"/> Product Development Protocol (PDP)</td> <td><input type="checkbox"/> Panel Track (PMA, PMR, PDP)</td> </tr> <tr> <td><input type="checkbox"/> Premarket Report (PMR)</td> <td><input type="checkbox"/> Real-Time (PMA, PMR, PDP)</td> </tr> <tr> <td></td> <td><input type="checkbox"/> 180-day (PMA, PMR, PDP)</td> </tr> </table>				<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party	3.1 Select one of the types below	<input type="checkbox"/> Biologics License Application (BLA)	<input checked="" type="checkbox"/> Original Application	<input type="checkbox"/> Premarket Approval Application (PMA)	Supplement Types:	<input type="checkbox"/> Modular PMA	<input type="checkbox"/> Efficacy (BLA)	<input type="checkbox"/> Product Development Protocol (PDP)	<input type="checkbox"/> Panel Track (PMA, PMR, PDP)	<input type="checkbox"/> Premarket Report (PMR)	<input type="checkbox"/> Real-Time (PMA, PMR, PDP)		<input type="checkbox"/> 180-day (PMA, PMR, PDP)
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	<input type="checkbox"/> 180-day (PMA, PMR, PDP)																
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: null																	
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0"> <tr> <td><input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms</td> <td><input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population</td> </tr> <tr> <td><input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only</td> <td><input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially</td> </tr> </table>				<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population	<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially										
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6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO																	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005) (b)																	

Form FDA 8601 (08/2003)

(Close Window)

16-May-2005

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Device Name

Device Trade Name: ArComXL™ Polyethylene Liners and BioloX® *delta* Heads
Common Name: Acetabular liners and Ceramic heads

Address and Registration Number

Manufacturer: Biomet Manufacturing Corp. (ArComXL™)
56 East Bell Drive
Warsaw, IN 46582
Establishment Registration #: 1825034

(b)(4)Trade Secret Process



Sterilization Site:

(b)(4)Trade Secret Process



Contact Person

Tracy Bickel Johnson, RAC
Manager of Regulatory Affairs
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46582
Phone: (574) 267-6639
FAX: (574) 372-1683
e-mail: tracy.johnson@biometmail.com

Device Class

Class: Class II
Device Product Code: LZ0
Classification Name(s): hip joint/ceramic/polymer, semi-constrained, cemented or non-cemented prosthesis (888.3353)
Panel: Orthopedics / 87
Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act.

Predicate Device Information

The predicate devices, ArComXL™ Polyethylene Liners (K042051), were cleared March 8, 2005. The BioloX® *delta* heads were previously cleared in K042091 (March 25, 2005).

Labeling

ArComXL™ and BioloX® *delta* labels and their respective inserts can be found in **Exhibit A**. There have been no changes to either the labeling or the package inserts since their previous clearance.

Indications for Use

The Indications for Use statements are as follows:

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.

Intended for cemented and uncemented applications

A copy of the Indications for Use Statement can be found in **Exhibit B.**

Sterilization and Packaging

ArComXL™ Acetabular Liners are provided sterile as follows:

1. Sterilant- Hydrogen Peroxide Gas Plasma
2. Equipment- (b)(4)Trade Secret
3. Sterility Assurance Level: 10⁻⁶
4. Sterility Validation Method: (b)(4)Trade Secret
5. Pyrogen-Free: No claims will be made
Packaging: Each component is placed within a single Tyvek® pouch. They are then placed in an outer blister pack, sealed with a Tyvek® lid. The entire unit is placed in a cardboard box and shrink wrapped for protection.
6. Labeling: All packages will display a red to blue chemical indication dot along with a statement that the device has been sterilized.

BioloX® delta Ceramic Heads are provided sterile by the radiation method as follows:

1. Radiation Type: Gamma
Radiation Source: Cobalt 60
Minimum Dosage: 25 kGy
Maximum Dosage: 40 kGy
2. Sterility Assurance Level: 10⁻⁶
3. Sterility Validation Method: TIR27 VDmax
4. Pyrogen-Free: No claims will be made
5. Packaging: Each component is placed within a plastic bag between two foam pads. They are then placed in an inner blister pack sealed with a Tyvek® lid that fits into an outer blister pack also sealed with a Tyvek® lid. The entire unit is placed in a cardboard box and shrink wrapped for protection.
6. Labeling: All packages will display a yellow to red chemical indication dot along with a statement that the device has been sterilized by gamma irradiation, 25 kGy.

*All trademarks are property of Biomet, Inc. except for the following:
Tyvek is a trademark of E.I. duPont de Nemours and Company*

Device Description

ArComXL™

The ArComXL™ Acetabular Liners are manufactured from highly cross-linked polyethylene conforming to ASTM F648 that was previously cleared in K042051. ArComXL™ Acetabular Liners are offered in three designs: MaxRom, Hi-Wall, and 10°. The designs are available in inner diameters of 28, 32, and 36mm. All designs utilize the RingLoc® locking mechanism. The product listing and mechanical drawings can be found in **Exhibit C.**

21

BioloX[®] delta

BioloX[®] delta Ceramic Heads (K042091) are composed of Transition-Toughened-Platelet-Alumina (TTPA). The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper. This submission covers modular heads 28mm in diameter with neck lengths of -3, 0, +3, and +5, while the 32mm has neck lengths of -3, 0, +3, and +6. **Exhibit C** contains the product listing and mechanical drawings.

Exhibit D contains a listing of compatible products (i.e. stems and shells) that can be utilized by the ArComXL[™] Acetabular Liners and BioloX[®] delta Ceramic Heads. These stems and shell listings are the same as in the predicate 510(k)'s.

Design Transfer/ Process Controls: Typically evidence of design transfer is indicated by sign-off on the engineering drawings by engineering, manufacturing, and quality assurance personnel. Design transfer for a process change is demonstrated by process validation. This information is included in the design history file Product Development Record 4.0.1.1, Section 2 (Biomet, Warsaw, IN). Biomet Manufacturing Corp. will also be using quality system standards as a basis for design transfer and maintenance of process controls.

Discussion of Differences

The modifications made to the predicate device(s) are as follows:

- All materials, designs, sizes, and processes for ArComXL[™] and BioloX[®] delta Ceramic Heads have been previously cleared in K042051 and K042091. This submission is solely for the ability to use the two products (ArComXL[™] and BioloX[®] delta) together. Previously, BioloX[®] delta Ceramic heads were cleared for use with traditional ArCom[®] polyethylene components while, the ArComXL[™] Acetabular liners were previously cleared using CoCr heads.

Summary of Design Control Activities

The risk assessment has been conducted to determine the impact of the modifications. Risks identified are presented in **Exhibit E** along with the associated verification activities and results.

A declaration of conformity with design control is included in **Exhibit F**.

Mechanical Testing

(b)(4)Trade Secret Process

abrasive conditions. A copy of the test report can be found in **Exhibit G**.

(b)(4)Trade Secret Process

as compared to articulating against CoCr. See **Table 1** for a comparison of the volumetric wear rates.

The combinations of utilizing a BioloX[®] delta femoral head and ArComXL[™] Acetabular Liners showed a (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

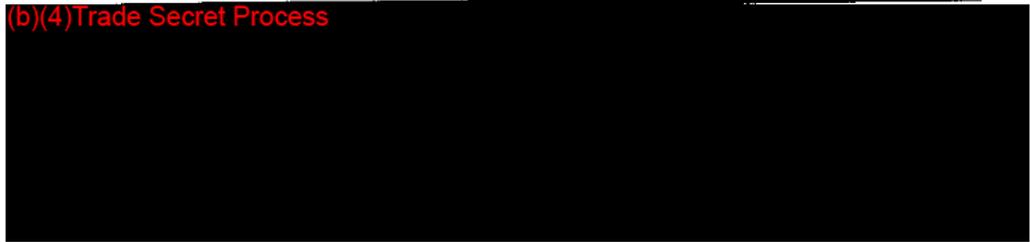
**Substantial
Equivalence**

The devices ArComXL™ Acetabular Liners and BioloX® *delta* Ceramic Heads, have the following similarities to those which have previously received 510(k) concurrence:

- *The devices have the same 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.
- *The devices are intended for cemented and uncemented applications.*
- *Incorporate the same designs and sizes:*
 - ArComXL™ acetabular liners designs include, MaxRom, Hi-Wall, and 10° liners. All liners are available in 28, 32, and 36mm inner diameters.
 - BioloX® *delta* ceramic 28mm and 32mm heads have the following neck lengths -3, 0, +3, +5 (28mm only), and +6 (32mm only).
- *Are manufactured from the same materials:*
 - ArComXL™ acetabular liners is composed of highly crosslinked UHMWPE
 - BioloX® *delta* Ceramic Heads is composed of Transition-Toughened-Platelet- Alumina (TTPA).
- *Volumetric Wear Testing:*

(b)(4)Trade Secret Process

(b)(4) Trade Secret Process



Based on the information provided in this submission, there are no new issues regarding the safety and/or efficacy of the abovementioned devices.

510(k) Summary

A 510(k) Summary is included in **Exhibit H**.

Truthful and Accuracy Certification

A certification of the truthfulness and accuracy is provided in **Exhibit I**.

PRODUCT LABELS

ArComXL™ Label

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
 P.O. BOX 587 WARSAW, IN 46581 USA
REF. XL-105882
MAX-ROM(TM) RINGLOC(R)
28MM ACETABULAR LINER
SIZE 22 / STANDARD

ARCOMXL(TM) UHMWPE
PATENT # 6,168,626

LOT 123123
 AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
 P.O. BOX 587 WARSAW, IN 46581 USA
REF. XL-105882
MAX-ROM(TM) RINGLOC(R)
28MM ACETABULAR LINER
SIZE 22 / STANDARD

ARCOMXL(TM) UHMWPE
PATENT # 6,168,626

LOT 123123
 AFFIX TO PATIENT RECORDS

REF. XL-105882 **LOT 123123**
MAX-ROM(TM) RINGLOC(R)
28MM ACETABULAR LINER
SIZE 22 / STANDARD

ARCOMXL(TM) UHMWPE
PATENT # 6,168,626

LOT 123123

QTY. 1

CE 0086

STERILE
 2005-05

EXPIRY DATE:
 2010-05



BIOMET ORTHOPEDICS, INC.
 56 EAST BELL DRIVE
 P.O. BOX 587
 WARSAW, IN 46581 USA

Biolox® delta Label

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
 P.O. BOX 587 WARSAW, IN 46581 USA
REF. 12-115109
BIOLOX-DELTA MODULAR CERAMIC HEAD
28MM HEAD DIAMETER
MINUS 3 NECK TYPE 1 TAPER
ALUMINA / ZIRCONIA

LOT 123123
 AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
 P.O. BOX 587 WARSAW, IN 46581 USA
REF. 12-115109
BIOLOX-DELTA MODULAR CERAMIC HEAD
28MM HEAD DIAMETER
MINUS 3 NECK TYPE 1 TAPER
ALUMINA / ZIRCONIA

LOT 123123
 AFFIX TO PATIENT RECORDS

REF. 12-115109 **LOT 123123**
BIOLOX-DELTA MODULAR CERAMIC HEAD
28MM HEAD DIAMETER
MINUS 3 NECK TYPE 1 TAPER
ALUMINA / ZIRCONIA

Biolox is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



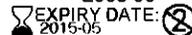
BIOMET ORTHOPEDICS, INC.
 56 EAST BELL DRIVE
 P.O. BOX 587
 WARSAW, IN 46581 USA

STERILE R

2005-05

EXPIRY DATE:
 2010-05

CE 0086



Biomet® Hip Joint Replacement Prostheses
ArComXL™ Highly Crosslinked Polyethylene

Attention Operating Surgeon

DESCRIPTION

Acetabular liners are composed of UHMWPE and are manufactured into various designs and sizes. The acetabular liners are utilized with other hip prostheses as part of a total joint system. Total hip joint prostheses include: femoral stems, femoral heads, acetabular shells, and acetabular liners. Components are available in numerous designs and sizes intended for primary and/or revision applications. Specialty components that can be added to the total hip system include: acetabular screws, centering sleeves, and canal plugs.

Materials

Acetabular Liners ArComXL™ highly crosslinked Ultra High Molecular Weight Polyethylene (UHMWPE)

INDICATIONS

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.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity level, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

WARNINGS

Improper selection, placement, positioning, alignment and/or fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture, and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments prior to performing surgery.

1. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
2. Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
3. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.

Biomet joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal, healthy bone, and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma, and/or weight gain have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

PRECAUTIONS

Specialized instruments are designed for Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear, and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been placed in a different patient, even if momentarily.

POSSIBLE ADVERSE EFFECTS

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
2. Early or late postoperative, infection, and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and/or excessive activity.
5. Periarticular calcification or ossification with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, and/or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
13. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14. Postoperative bone fracture and pain.

STERILITY

Prosthetic components are sterilized by exposure to one of the following methods:

- Ethylene Oxide Gas (EtO)
- Gas Plasma

Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax 574-372-1683.

Authorized Representative: Biomet, U.K., Ltd.
Waterton Industrial Estates,
Bridgend, South Wales
CF31 3XA U.K.

CE 0086

Biomet TTPA Ceramic Modular Head Hip Joint Prostheses

Attention Operating Surgeon

DESCRIPTION

Biomet ceramic modular head components are a Transition-Toughened-Platelet Alumina Composite ceramic (TTPA) material with highly polished surfaces. Ceramic heads are available in a variety of head sizes and neck length variations. The highly polished surface is designed to reduce friction and minimizes wear.

MATERIALS

TTPA Ceramic

INDICATIONS

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 throchanteric fractures of the proximal femur with head involvement, unmanageable using techniques other than joint replacement.
5. Revision procedures where other devices or treatments have failed.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

WARNINGS

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue, have lower adhesion strength to cement than implants handled with clean gloves. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

1. Use TTPA ceramic modular head with Biomet metallic femoral components. Do not use Biomet TTPA ceramic modular heads with femoral stems or acetabular components offered by other manufacturers. Mismatching of components or taper sizes can be expected to cause intraoperative or postoperative fracture of ceramic heads.
2. Ceramic heads labeled "Type I Taper" are to be used with femoral stem components labeled "Type I Taper".
3. Use only with Ultra-High Molecular Weight Polyethylene (UHMWPE) or metal backed UHMWPE acetabular components.
4. Do not use ceramic heads that have been dropped, rubbed, scratched, or disfigured. Blemishes can be expected to cause failure.
5. Do not use a metallic hammer when seating the ceramic head. Use a nylon or polyethylene seating instrument. Do not use excessive force. The TTPA ceramic head can fracture with excessive force.
6. The femoral stem trunion and the bore of the ceramic head should be dry and free of contamination prior to assembly.

Biomet joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient

is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

PRECAUTIONS

Specialized instruments are designed for Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, and/or excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity levels, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

POSSIBLE ADVERSE EFFECTS

Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.

1. Early or late postoperative, infection, and allergic reaction.
2. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
3. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, non-union, bone resorption, and excessive activity.
4. Periarticular calcification or ossification, with or without impediment of joint mobility.
5. Inadequate range of motion due to improper selection or positioning of components.
6. Undesirable shortening of limb.
7. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
8. Fretting and crevice corrosion can occur at interfaces between components.
9. Wear and/or deformation of articulating surfaces.
10. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
11. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
12. The TTPA ceramic modular head is composed of ceramic material with limited clinical history. Although mechanical testing demonstrates that, when used with polyethylene acetabular components, ceramic balls produce a relatively low amount of particles, the total amount of particulate produced remains undetermined. Because of the limited clinical and preclinical experience, the long-term biological effects of these particulates are unknown.
13. Intraoperative and postoperative bone fracture and/or postoperative pain.
14. Ceramic head fractures have been reported.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, P.O. Box 587, Warsaw, IN 46582 USA, FAX: 574-372-1683.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estates,
Bridgend, South Wales
CF31 3XA, U.K.

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
(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)

PART NUMBER LISTING FOR ARCOMXL™ ACETABULAR LINERS

Part Number	ArComXL™ Description	Size
XL-105882	ArComXL™ 28mm RNLGLC LNR MROM	SZ 22
XL-105883	ArComXL™ 28mm RNLGLC LNR MROM	SZ 23
XL-105884	ArComXL™ 28mm RNLGLC LNR MROM	SZ 24
XL-105885	ArComXL™ 28mm RNLGLC LNR MROM	SZ 25
XL-105886	ArComXL™ 28mm RNLGLC LNR MROM	SZ 26
XL-105887	ArComXL™ 28mm RNLGLC LNR MROM	SZ 27
XL-105888	ArComXL™ 28mm RNLGLC LNR MROM	SZ 28
XL-105933	ArComXL™ 32mm RNLGLC LNR MROM	SZ 23
XL-105934	ArComXL™ 32mm RNLGLC LNR MROM	SZ 24
XL-105935	ArComXL™ 32mm RNLGLC LNR MROM	SZ 25
XL-105936	ArComXL™ 32mm RNLGLC LNR MROM	SZ 26
XL-105937	ArComXL™ 32mm RNLGLC LNR MROM	SZ 27
XL-105938	ArComXL™ 32mm RNLGLC LNR MROM	SZ 28
XL-105994	ArComXL™ 36mm RNLGLC LNR MROM	SZ 24
XL-105995	ArComXL™ 36mm RNLGLC LNR MROM	SZ 25
XL-105996	ArComXL™ 36mm RNLGLC LNR MROM	SZ 26
XL-105997	ArComXL™ 36mm RNLGLC LNR MROM	SZ 27
XL-105998	ArComXL™ 36mm RNLGLC LNR MROM	SZ 28
XL-105902	ArComXL™ 28mm RNLGLC LNR HW	SZ 22
XL-105903	ArComXL™ 28mm RNLGLC LNR HW	SZ 23
XL-105904	ArComXL™ 28mm RNLGLC LNR HW	SZ 24
XL-105905	ArComXL™ 28mm RNLGLC LNR HW	SZ 25
XL-105906	ArComXL™ 28mm RNLGLC LNR HW	SZ 26
XL-105907	ArComXL™ 28mm RNLGLC LNR HW	SZ 27
XL-105908	ArComXL™ 28mm RNLGLC LNR HW	SZ 28
XL-105923	ArComXL™ 32mm RNLGLC LNR HW	SZ 23
XL-105924	ArComXL™ 32mm RNLGLC LNR HW	SZ 24
XL-105925	ArComXL™ 32mm RNLGLC LNR HW	SZ 25
XL-105926	ArComXL™ 32mm RNLGLC LNR HW	SZ 26
XL-105927	ArComXL™ 32mm RNLGLC LNR HW	SZ 27
XL-105928	ArComXL™ 32mm RNLGLC LNR HW	SZ 28
XL-105914	ArComXL™ 36mm RNLGLC LNR HW	SZ 24
XL-105915	ArComXL™ 36mm RNLGLC LNR HW	SZ 25
XL-105916	ArComXL™ 36mm RNLGLC LNR HW	SZ 26
XL-105917	ArComXL™ 36mm RNLGLC LNR HW	SZ 27
XL-105918	ArComXL™ 36mm RNLGLC LNR HW	SZ 28

Part Number	ArComXL™ Description	Size
XL-105811	ArComXL™ 28mm RNLGC LNR 10 Deg	SZ 21
XL-105812	ArComXL™ 28mm RNLGC LNR 10 Deg	SZ 22
XL-105813	ArComXL™ 28mm RNLGC LNR 10 Deg	SZ 23
XL-105814	ArComXL™ 28mm RNLGC LNR 10 Deg	SZ 24
XL-105815	ArComXL™ 28mm RNLGC LNR 10 Deg	SZ 25
XL-105816	ArComXL™ 28mm RNLGC LNR 10 Deg	SZ 26
XL-105817	ArComXL™ 28mm RNLGC LNR 10 Deg	SZ 27
XL-105818	ArComXL™ 28mm RNLGC LNR 10 Deg	SZ 28
XL-105833	ArComXL™ 32mm RNLGC LNR 10 Deg	SZ 23
XL-105834	ArComXL™ 32mm RNLGC LNR 10 Deg	SZ 24
XL-105835	ArComXL™ 32mm RNLGC LNR 10 Deg	SZ 25
XL-105836	ArComXL™ 32mm RNLGC LNR 10 Deg	SZ 26
XL-105837	ArComXL™ 32mm RNLGC LNR 10 Deg	SZ 27
XL-105838	ArComXL™ 32mm RNLGC LNR 10 Deg	SZ 28
XL-105894	ArComXL™ 36mm RNLGC LNR 10 Deg	SZ 24
XL-105895	ArComXL™ 36mm RNLGC LNR 10 Deg	SZ 25
XL-105896	ArComXL™ 36mm RNLGC LNR 10 Deg	SZ 26
XL-105897	ArComXL™ 36mm RNLGC LNR 10 Deg	SZ 27
XL-105898	ArComXL™ 36mm RNLGC LNR 10 Deg	SZ 28

PART NUMBER LISTING FOR BIOLOX® DELTA CERAMIC HEADS

Biomet Part Number	BioloX® delta Description
12-115109 (RD115109)	TTPA Head Taper Type I, -3mm x 28mm
12-115110 (RD115110)	TTPA Head Taper Type I, std x 28mm
12-115111 (RD115111)	TTPA Head Taper Type I, +3mm x 28mm
12-115112 (RD115112)	TTPA Head Taper Type I, +5mm x 28mm
12-115114 (RD115114)	TTPA Head Taper Type I, -3mm x 32mm
12-115115 (RD115115)	TTPA Head Taper Type I, std x 32mm
12-115116 (RD115116)	TTPA Head Taper Type I, +3mm x 32mm
12-115117 (RD115117)	TTPA Head Taper Type I, +6mm x 32mm

(b)(4) Trade Secret Process

Classifications for devices in table

1. Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310) Product Code: KWZ
2. Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21 CFR 888.3320) Product Code: JDL
3. Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR 888.3330) Product Code: KWA
4. Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350) Product Code: JDI
5. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353) Product Code: LZO, MEH
6. Hip joint metal/polymer/metal semi-constrained, porous-coated, uncemented prosthesis (21 C.F.R. 888.3358) Product Code: LPH
7. Hip joint (hemi-hip) acetabular metal cemented prosthesis (21 CFR 888.3370)
8. Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390) Product Code: KWY

The Acetabular Components contained in this submission may be used with Biomet femoral components cleared under the following 510(k)s:

Femoral Component Name	510(k) Number	Product Code	(b)(4) Trade Secret Process	Indication
Answer® Femoral Component	K991987	JDI		Cemented
Co-Cr Answer® Femoral Components	K931194	JDG ¹		Cemented
APF Femoral Component	K852585 K984154 K030055	JDI JDI LPH		Cemented and non-cemented
Bi-Metric® Femoral Components	K921224 K020580 K030055	LZO LPH LPH		Cemented and non-cemented
Bi-Metric® Head/Neck Replacement	K955350 K992058 K983710	LZO JDI JDI		Cemented
HA Bi-Metric® Femoral Component	K023409 K030055	LPH LPH		Non-cemented
Bio-Groove® Hip Component	K864085	KWL ²		Non-cemented
Bio-Groove® HAP Hip Components	K912369 K912370	MEH MEH		Non-cemented
Bohn Femoral Component	K000262	LZO, MEH		Non-cemented
Buchalter/Fausser Femoral Component	K952686	LZO		Cemented
Color Buffed Cemented stem	K992903 K012019	JDI JDI		Cemented
Fenning (Osteocap RS®) Femoral Component	K960303	LPH		Non-cemented
Fine Grain Cast Cobalt Chromium Hip	K953925	LZO		Cemented
Generation 4 Polished Femoral Hip Prosthesis	K031734	JDI		Cemented
Gross Femoral Component	K001580	MEH		Non-cemented
Impact® Co-Cr Femoral Components	K942027	JDG ³		Cemented
Integral® Femoral Component	K921225 K984296 K984408 K030055 K030501 K042029	LZO LPH LPH LPH LPH LPH		Cemented and non-cemented
Integral® Co-Cr Femoral Component	K942479	LZO		Cemented
Interlocking Hip Stems	K990830 K042774	LPH LPH ⁴		Non-cemented
Mallory/Head® Total Hip System	K921181 K994007 K000538 K003429 K030055	LZO JDI LPH LPH LPH		Cemented and non-cemented
HA Mallory/Head® Total Hip System	K021403	LPH, MEH		Non-cemented

¹ Submitted under classification 888.3350 JDI

² Not stated in submission

³ Submitted under classification 888.3350 JDI

⁴ Cleared under product codes JDL, KWA, LPH, LZO, KWZ, JDI and KQY based on available modular head and acetabular components for use with this stem

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	K030055	LPH, MEH	(b)(4) Trade Secret Process	
Mallory/Head® Co-Cr Femoral Component	K911684	JDI		Cemented
Mallory/Head® Calcar Femoral Components (including HA)	K945115 K001660 K031693	LPH LPH LPH		Cemented and non-cemented
Medallion Hip	K041850	LPH		Uncemented
Modular Hip Stems	K912712 K921274 K030055	JDI LPH LPH		Cemented and non-cemented
Oncology Salvage System	K002757	JDI		Cemented
OSS™ Les Proximal Femoral Component	K021380	JDI		Cemented and non-cemented
PMI® Femoral Component	K911802 K923452 K030055	JDI LPH LPH		Cemented and non-cemented
HA PMI® Femoral Stem	K030048	LPH		Non-cemented
Portrait™ Femoral Component	K010560	LZO		Non-cemented
Reach® Femoral Component	K971824 K982367 K000760	LPH LPH LPH		Non-cemented
Modular Reach®	K994038	LPH		Non-cemented
HA Modular Reach®	K022463 K030055	LPH LPH		Non-cemented
Rx-90® Femoral Stems	K942028 K023085	JDG ⁵ JDI		Cemented
SHP™ Hip System	K960984	JDI		Cemented
Taperloc® Femoral Component	K921301 K030055	LPH LPH		Cemented and non-cemented
HA Taperloc® Femoral Component	K020963 K030055	MEH LPH		Non-cemented
Total IM Femur	K033871	JDI		Cemented
Total Femur	K974558	JDI		Cemented

⁵ Submitted under classification 888.3350 JDI

The Femoral (or Modular Head) Components contained in this submission may be used with Biomet acetabular components cleared under the following 510(k)s:

Acetabular System Name	510(k) number	Product Code	Indications
A-B Acetabular System	K954417 K030055	LPH LPH	Cemented and non-cemented
All-Poly Acetabular Components	Preamend- ment		Cemented
ARCOM® Ringloc® Liners	K926107 K950761 K970501 K023357 K030055	LPH JDI LPH LPH LPH	Indication based on mating shell
ARCOM® Ringloc® Low Profile Liners	K926107 K970501 K023357	LPH LPH LPH	Indication based on mating shell
ARCOM XL™ Polyethylene Liners	K042051	JDI, LPH	Cemented and non-cemented
Bio-Clad™ All-Poly	K926107	LPH	Cemented
Flanged Acetabular Component	K983035 K030055	LPH LPH	Cemented and non-cemented
Freedom® Constrained All Poly Cups	K030047	KWZ	Cemented
Freedom® Constrained Liners	K030047	KWZ	Indication based on mating shell
Full Hemisphere Acetabular Components	K920640	JDL*	Cemented
Healy™ Flanged Revision	K921139	JDL*	Cemented
Index® Acetabular Components	K950761 K030055	JDI LPH	Cemented and non-cemented
M ² a-38™ Acetabular Shells	K011110	KWA	Non-cemented
M ² a-Magnum™ System	K042037	KWA	Non-cemented
M ² a-Ringloc™ Acetabular Shells	K002379	KWA	Non-cemented
M ² a-Taper™ Acetabular Shells	K993438 K003363 K042841	KWA KWY JDL	Cemented and non-cemented
Mallory/Head® Acetabular Components	K861114 K921181 K030055	JDL* LZO LPH	Cemented and non-cemented
Mars® Modular Acetabular Reconstructive System	K911718	JDI	Cemented
Par 5™ Acetabular Components	K022094	JDI	Cemented and non-cemented
Pegged (TRI-SPIKE™) Acetabular Components	K970501 K030055	LPH LPH	Cemented and non-cemented
Protrusio Cages	K971890 K020076	JDI JDI	Cemented
Ranawat/Burstein® Acetabular Components	K911685 K921277	JDI LPH	Cemented and non-cemented (NIDJD only)
Ringloc® Bi-Polar Acetabular Components	K833175	KWY	N/A
Ringloc® Constrained Liner	K021728	KWZ	Indication based on mating shell

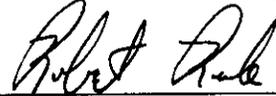
RX 90® Low Profile Acetabular Components	K920639 K042989	JDL* LPH, LZO, JDI, KWZ, MEH	Cemented and non-cemented
Tri-Polar Acetabular System including liners	K991990	KWY	Cemented and non-cemented
Universal® Acetabular Components	K861433 K921301 K030055	JDL* LPH LPH	Cemented and non-cemented

*The JDL product code for metal on metal, cemented components (21 CFR 888.3320) is listed in the FDA's web database for these submissions. All of these submission were for metal on polyethylene systems (JDI).

Declarations Of Conformity With Design Controls
ArComXL™ Polyethylene Liners and BioloX® *delta* Ceramic Heads

**Verification
Activities**

To the best of my knowledge, all verification and validation activities were performed by the designated individual(s) and the result of the activities demonstrated that the predetermined acceptance criteria were met.



Robert Ronk
Director of Biomaterials Engineering
Biomet Manufacturing Corp.

5-25-05

Date

**Manufacturing
Facility**

The manufacturing facility, Biomet, Inc., is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.



Rex A. White
Director of Compliance
Biomet Manufacturing Corp.

27 May '05

Date

510(k) SUMMARY

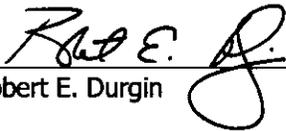
- Sponsor:** Biomet Manufacturing Corporation
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587
- Contact Person:** Tracy Bickel Johnson, RAC
- Proprietary Name:** ArComXL™ Acetabular Liners and BioloX® delta Ceramic Heads
- Common Name:** Acetabular liners and ceramic heads
- Classification Name:** 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.

All trademarks are property of Biomet, Inc.

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87(j))**

ArComXL™ Polyethylene Liners and BioloX® delta Ceramic Heads

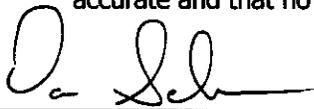
I certify, in my capacity as Vice President, Regulatory Affairs and Quality Assurance, Biomet, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Robert E. Durgin

26 MAY 05
Date

I certify, in my capacity as Chief Scientist, Biomet Manufacturing Corp., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Dave Schroeder

May 26, 2005
Date

From: Reviewer(s) - Name(s) Jonathan Lim

Subject: 510(k) Number K051411

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N/A

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

L20 II

Review: Henry Stegman ORDB 6/29/05
(Branch Chief) (Branch Code) (Date)

Final Review: Steph Pluvins 6/29/05
(Division Director) (Date)

SPECIAL 510(K) MEMORANDUM

TO: K051411
FROM: Jonathan Lim *J. Lim 6/24/05*
Biomedical Engineer, FDA/CDRH/ODE/DGRND/ORDB
DATE: 06/24/2005
SUBJECT: Biomet ArComXL Polyethylene Liners and BioloX Delta Heads
Product/Panel Code: LZO Class: II Classification: 21CFR 888.3353

RECOMMENDATION SUMMARY:

I recommend that the Biomet ArComXL Polyethylene Liners and BioloX Delta Heads to be found **substantially equivalent** to legally marketed devices.

J. Lim 6/24/05

I. COMPANY IDENTIFICATION:

Proprietary Name: Biomet ArComXL Polyethylene Liners and BioloX Delta Heads
Applicant/Sponsor: Biomet, INC.
Address: 56 East Bell Drive.
P.O. Box 587
Warsaw, IN 46582
Phone Numbers: (574) 267-6639
Fax: (574) 372-1683
Contact Person: Tracy Bickel Johnson

II. PREDICATE DEVICE(S):

K042051	Biomet ArComXL Polyethylene Liners	Biomet, INC.
K042091	Biomet BioloX delta heads	Biomet, INC.

III. INTENDED USE/INDICATIONS:

- 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.

Comparison with Predicates: These Indications for Use are identical to those in the cleared predicate devices Biomet ArComXL Polyethylene Liners (K042051) and Biomet BioloX delta heads (K042091).

IV. DEVICE DESCRIPTION & MATERIALS:

General Device and Material Description

The ArComXL polyethylene liners are manufactured from highly crosslinked polyethylene conforming to ASTM F648 that was previously cleared in K042051. ArComXL is available in three designs: MaxRom, Hi-Wall, and 10°. The designs are available in inner diameters of 28, 32, and 36mm. All designs utilize the RingLoc locking mechanism.

BioloX delta Ceramic Heads are composed of Transition-Toughened-Platelet-Alumina (TTPA). The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper. This submission covers modular heads 28mm in diameter with neck lengths of -3, 0, +3, and +5, while the 32mm has neck lengths of -3, 0+3, and +6.

This submission is solely for the ability to use the two products (ArComXL and BioloX delta) together. In previous submissions, BioloX delta Ceramic heads were cleared for use with traditional ArCom polyethylene components, while the ArComXL Acetabular liners were previously cleared using CoCr heads.

V. STERILITY AND PACKAGING:

The ArComXL polyethylene liners will be sold sterile. Each component is placed within a single Tyvek pouch. They are then placed in an outer blister pack, sealed with a Tyvek lid. The entire unit is placed in a cardboard box and shrink-wrapped for protection.

Method of sterilization: (b)(4)Trade Secret Process - Testing Report
 Method of Validation: (b)(4)Trade
 Sterility Assurance Level: 10⁻⁶

The BioloX delta Ceramic Heads will be sold sterile. Each component is placed within a plastic bag between two foam pads. They are then placed in an inner blister pack, sealed with a Tyvek lid that fits into an outer blister pack also sealed with a Tyvek lid. The entire unit is placed in a cardboard box and shrink-wrapped for protection.

Method of sterilization: (b)(4)Trade Secret Process
 Method of Validation: (b)(4)Trade
 Cycle: Overkill
 Dosage: 25 Kilograys/2.5 Mrad minimum, 40 Kilograys/4.0 Mrad maximum
 Sterility Assurance Level: 10⁻⁶

These products are for single use only. No claim of non-pyrogenicity is made and no pyrogen testing is conducted.

VI. LABELING:

The sponsor's draft package label is provided in Exhibit A of the submission.

VII. PACKAGE INSERT:

The sponsor's draft package insert is provided in Exhibit A of the submission.

VIII. 510K SUMMARY:

The sponsor has provided an adequate summary.

IX. PERFORMANCE DATA:

The sponsor has provided a comparison analysis of wear rates between ArCom and ArComXL Coupled with CoCr and BioloX Delta modular heads. Each polyethylene material was tested against both metal and ceramic modular heads. The metal heads are the standard CoCr material. The ceramic heads are zirconia-toughened alumina (BioloX Delta), which are supplied by (b).

Testing was performed according to ASTM F1714-96, "Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in simulator Devices."

X. RISK ANALYSIS

<i>Change</i>	<i>Risk</i>	<i>Verification Activities</i>	<i>Acceptance Criteria</i>	<i>Results of Verification</i>
---------------	-------------	--------------------------------	----------------------------	--------------------------------

(b)(4)Trade Secret Process - Testing Report

XI. SE DETERMINATION:

The sponsor has claimed SE to the following legally marketed devices:

K042051	Biomet ArComXL Polyethylene Liners	Biomet, INC.
K042091	Biomet BioloX delta heads	Biomet, INC.

The submission is to assess the safety and effectiveness of using the two products (ArComXL and BioloX delta) together. The comparative wear testing results indicate a lower wear rate in the combination of ArComXL liners with the BioloX Delta heads.

Under clean conditions, (b)(4)Trade Secret Process [REDACTED]

By changing (b)(4)Trade Secret Process [REDACTED]

The combination of ArComXL articulating with BioloX shows an (b)(4)Trade Secret Process [REDACTED]

Based on the similarities in the design, geometry, material and the results of the wear analysis, I recommend that this device be found substantially equivalent to other legally marketed predicate devices.

XII. CONTACT RECORD:

None

		YES	NO	
1.	Is Product A Device	Yes		If NO = Stop
2.	Is Device Subject To 510(k)?	Yes		If NO = Stop
3.	Same Indication Statement?	Yes		If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5.	Same Technological Characteristics?	Yes		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?		No	If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9.	Accepted Scientific Methods Exist?			If NO = Stop NE
10.	Performance Data Available?	Yes		If NO = Request Data
11.	Data Demonstrate Equivalence?	Yes		Final Decision: SE

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?	✓	
5. Is the product a device?		✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	
7. Is the device subject to review by CDRH?		✓
8. Are you aware that this device has been the subject of a previous NSE decision?	N/A	
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K051411

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **	✓	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	✓	
510(k) Kit Certification ***	✓	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:	✓	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: Jonathan Lin

Concurrence by Review Branch: Alan Sheg

Date: 6/28/05

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: Jonathan Lim
 Division/Branch: DGRND/ORDB
 Device Name: ArCom XL Polyethylene Liners and Biopak Delta Heads
 Product To Which Compared (510(K) Number If Known): K042051, K042091

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	✓		If NO = Request Data
11. Data Demonstrate Equivalence?	✓		Final Decision: <u>SE</u>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

See Memo

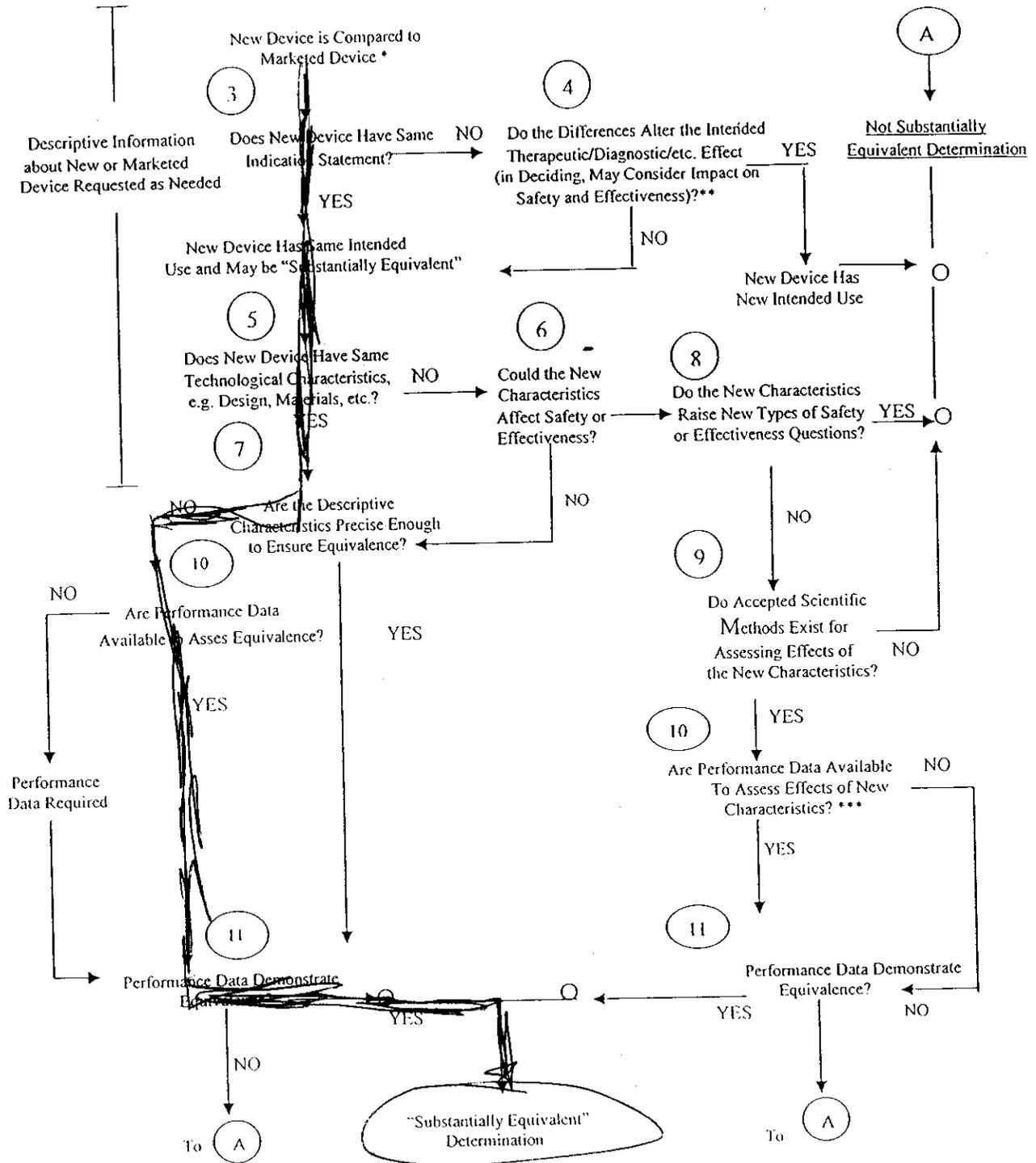
1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.