K110555

MAR 2 4 2011

BIOMET MANUFACTURING CORP.

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive Warsaw, IN 46581-0857
Phone number	(574) 267-6639
Fax number	(574) 372-1683
Establishment Registration Number	1825034
Name of contact person	Becky Earl
Date prepared	02/23/2011
Name of device	
Trade or proprietary name	ArComXL™ Active Articulation
Common or usual name	Artificial Hip Replacement Component--Acetabular
Classification name	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21CFR §888.3358)
Classification panel	Orthopedic
Regulation	21CFR §888.3358
Product Code(s)	LPH (888.3358), LZO (888.3353), KWY (888.3390)
Legally marketed device(s) to which equivalence is claimed	E1™ Avantage™ Head (E1™ Active Articulation), K101336
Reason for 510(k) submission	The ArComXL™ Active Articulation is only a material change from the predicate, offering more options to patient, hospital, and surgeon.
Device description	The ArComXL™ Active Articulation belongs to the family of dual mobility acetabular implants: the presence of two articulating surfaces in the same joint device. The ArComXL™ Active Articulation Head fits over a femoral modular head, which articulates within the ArComXL™ Head. The resultant assembly then articulates within the acetabular metal shell. The ArComXL™ Head is designed to be used with several styles of acetabular shells that have

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	been cleared in previous submissions: M²a Magnum™ (K042037), Magnum™ Tri-Spike (K062995), and M²a 38™ Flared Cups and Non-Flared Cups (K011110). The ArComXL™ Active Articulation Heads are available in sizes 44-66mm (*Note: Size 44-66mm references O.D. of mating shell; the actual head sizes are 38-60mm.*) and are manufactured from highly cross-linked polyethylene, conforming to ASTM F648. ArComXL™ is not a new material; the material and manufacturing process were cleared in K042051, ArComXL™ Polyethylene Liners, as well as subsequent submissions. The ArComXL™ Active Articulation is designed for both primary and total revision surgeries, where all device components associated with the wear couple are removed and replaced. The system is intended for uncemented applications.
Intended use of the device	The system is intended for uncemented applications.
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. 6. Dislocation risks. The ArComXL™ Active Articulation Head is a single-use implant, intended for uncemented applications.

Summary of the technological characteristics of the device compared to the predicate

Characteristic	***New Device***	***Predicate***
Design	The ArComXL Active Articulation™ Head fits over a femoral modular head, which articulates within the	K101336

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	ArComXL™ head. The resultant assembly then articulates within the acetabular metal shell.	
Material	ArComXL™, UHMWPE	K042051
Size Range	44mm to 66mm	K101336

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

Characteristic	***Standard/Test/FDA Guidance***	***Results Summary***
Push-In and Lever-Out	NA	Six samples, identical to final production product and tested in the same manner as the predicate demonstrated equivalence to the Bipolar/Tri-Polar predicate. (K991990)
Wear Testing	ISO 14242	As in the E1™ Active Articulation predicate (K101336), the ArComXL™ Active Articulation heads were tested for 5 million cycles and compared to the ArCom™ 36mm liners (K032396), the largest-sized, cleared ArCom™ liners. Acceptance criteria called for wear rates less than that of the ArCom liners; the testing demonstrated equivalence to K032396.

Comparative Performance Information Summary

Characteristic	***Requirement***	***New Device***	***Predicate Device***
Push-In and Lever Out	Meets or exceeds parameters	Meets parameters	K101336
Wear Testing	Meets or exceeds parameters	Meets parameters	K101336

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Push-In and Lever Out	Meets or exceeds parameters	Meets parameters	K991990
Wear Testing	Meets or exceeds parameters	Meets parameters	K032396

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information: Not applicable

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

No clinical testing was necessary for a determination of substantial equivalence.

The results of mechanical testing indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

BioMet Manufacturing Corp.
% Ms. Becky Earl
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

MAR 24 2011

Re: K110555
Trade/Device Name: ArComXL™ Active Articulation Head
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO, KWY
Dated: February 25, 2011
Received: February 28, 2011

Dear Ms. Earl:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110555

Device Name: ArComXL™ Active Articulation Head

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.
6. Dislocation risks.

The ArComXL™ Active Articulation Head is a single-use implant, intended for uncemented applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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