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BIOMET
MANUFACTURING CORP.

510(k) Summary

DEC 7 2010

Preparation Date: August 26, 2010

Applicant/Sponsor:
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587
Establishment Registration Number: 1825034

Contact Person:
Becky Earl
Regulatory Specialist

Proprietary Name: Arcos™ Interlocking Distal Stem

Common Name: Femoral Hip Revision Stem

Classification Name:

LPH— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)

KWA—Prosthesis, Hip, Semi-Constrained (Metal Uncemented Acetabular Component) (21 CFR 888.3330)

JDL— Prosthesis, Hip, Semi-Constrained (Metal Cemented Acetabular Component) (21 CFR 888.3320)

LZO—Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353)

KWZ—Prosthesis, Hip, Constrained, Cemented or Uncemented, Metal/Polymer (21 CFR 888.3310)

JDI— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350)

KWY—Prosthesis, Hip, Hemi-Femoral, Metal/Polymer, Cemented or Uncemented (21 CFR 888.3390)

MAY—Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous Cemented, Osteophilic Finish (21 CFR 888.3353)

MEH—Prosthesis, Hip, Semi-constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate (21 CFR 888.3353)

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www.biomet.com

Shipping Address:
56 E. Bell Drive
Warsaw, IN 46582

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K042774	Mallory-Head® Modular Calcar Stems with Interlocking Slots—Biomet
K090757	Biomet® Modular Femoral Revision System

Device Description:
The Arcos™ Interlocking Distal Stem was designed to be a part of the Arcos™ Modular Femoral Revision System, a modular system using interchangeable stems and proximal bodies commonly seen in femoral revision surgery. The proximal bodies consist of broached, calcar-replacing, and cone-style implants, made from Ti-6Al-4V (ASTM F-136) and featuring a roller hardened taper, is fully porous coated (Ti-6AL-4V, ASTM F-1580) with a fine buffed finish on the bullet-tip. The distal stems will be offered in a range of diameters from 15-26mm and lengths of 200mm, 250mm, and 300mm. The stems are offered in porous cylindrical with proximal taper and splined tapered designs. The stem provides holes for interlocking screws to provide temporary rotational stability. The system also includes auxiliary implants to aid in fixation. The system is intended for uncemented applications

Intended Use:
Indications for the Arcos™ Interlocking Distal Stem include:

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 Arcos™ Interlocking Distal Stems are single-use implants, intended for uncemented applications.

Summary of Technologies:
The Arcos™ Interlocking Distal Stems have the same technological characteristics as the predicates listed above, including the same roller hardened taper process, as well as the same titanium porous plasma spray (PPS®) outer-surface coating.

Testing:
The following testing was performed to determine substantial equivalence:

- The distal pot fatigue test was performed to verify stem strength in the smallest diameter distal implant design in the Arcos™ Femoral Revision System. As required in ISO 7206-8, six stems were shown to have sufficient strength to survive distal pot fatigue testing to 5 million cycles. Since the smallest design in the Arcos™ Interlocking Distal Stems product line is a 15mm bullet-tipped stem, the previous testing of the worst case adequately confirms the strength of the smallest stem within this product line.
- The Kaessmann Transverse Screws, cleared in K9829953, were tested for use with femoral implants two separate times. The test performed was a torsional fatigue test to determine the ability of the screws to provide temporary rotational stability, as stated in the package insert.

The results indicated that the device was functional within its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomed Manufacturing Corp.
% Ms. Becky Earl
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Warsaw, IN 46581

DEC 7 2010

Re: K100469
Trade/Device Name: Arcos™ Interlocking Distal Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA, LPH, JDL, LZO, KWZ, JDI, KWY, MAY, MEH
Dated: August 26, 2010
Received: November 17, 2010

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

DEC 7 2010

Indications for Use

510(k) Number (if known): K100469 (pg 1/1)

Device Name: Arcos™ Interlocking Distal Stems

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 Arcos™ Interlocking Distal Stems are single-use implants, 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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