



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Biomet Incorporated
% Mr. Paul Cutlan
Regulatory Affairs Manager (Hips)
Waterton Industrial Estate
Bridgend, Bridgend CF31 3XA
UNITED KINGDOM

October 6, 2015

Re: K151603

Trade/Device Name: Acros One-piece Femoral Revision System

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Regulatory Class: Class II

Product Code: LPH, LZO, KWL, LWJ, KWZ, JDI, OQG, OQH, OQI, PBI, KWY

Dated: September 15, 2015

Received: September 17, 2015

Dear Mr. Cutlan:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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 -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K151603

Device Name

Arcos One-piece Femoral Revision System

Indications for Use (Describe)

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 procedures where other treatment or devices have failed.

The Arcos One-Piece Femoral Revision System hip components are single-use implants, intended for uncemented use only.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Arcos One-piece Femoral Revision System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0857
Phone Number: (574) 267-6639
Fax Number: (574) 371-1027

Establishment Registration Number: 1825034

Contact: Paul Cutlan
Regulatory Affairs Manager

Date: October 2nd 2015

Subject Device: Trade Name: Arcos One-piece Femoral Revision System
Common Name: Hip Prosthesis

Classification Name:

- LPH - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358)
- LZO - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)
- KWL - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360)
- LWJ - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360)
- KWZ - Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)
- JDI - Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350)

- OQG - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358)
- OQH - Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350)
- OQI - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)
- PBI – Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)
- KWY - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390)

Legally marketed device(s) to which equivalence is claimed:

- K090757 Modular Femoral Revision System (Arcos) (Biomet)
- K000760 Reach Femoral Component (Biomet)

Reference Devices:

Labeling and Biocompatibility:

- K143009 Echo Bi-Metric Microplasty Hip Stem (Biomet).

Implant Materials/Instrument materials/Type I taper Trunnion:

- K150503 Echo Bi-Metric Microplasty Line Extension (Biomet).

Implant Stem Diameters:

- K070274 Echo Bi-Metric Press Fit Stems (Biomet).

Device Description:

The Arcos One-piece Femoral Revision System is to be used as a femoral stem component in hip replacement surgery. The system is designed for both primary and revision total hip and hemi hip arthroplasty. All implants included in this system are intended for single use only. The system also includes implant specific instrumentation for all stem variants.

Intended Use and 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 procedures where other treatment or devices have failed.

The Arcos One-piece Femoral Revision System hip components are single-use implants, intended for uncemented use only.

Summary of Technical Characteristics:

The rationale for substantial equivalence is based on consideration of the following:

- The technological characteristics of the Arcos One-piece Femoral Revision System are the same as those of predicate devices (K090757 and K000760) in terms of design, material, and principle of operation with the exception of slight modifications as described within the 510(k).
- The Arcos One-piece Femoral Revision System is a monolithic variant of the Modular Femoral Revision System (Arcos) (K090757). Like the modular system, the Arcos One-piece is designed as a porous-coated femoral stem available in multiple lengths and proximal bodies for primary and revision procedures.

Summary of Performance Data (Non-clinical and/or Clinical) :**Non-clinical Tests:**

- Femoral Stem Fatigue
- Range of Motion

Clinical Tests:

None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion:

The proposed Arcos One-piece Femoral Revision System has the same intended use and similar indications for use as the predicate devices. The proposed device has similar technological characteristics to the predicates, and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the marketed predicate device.