K121874

BIOMET INC

NOV 23 2012

## 510(k) Summary

**Preparation Date:** August 23, 2012

**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:** G7™ Acetabular System

**Common Name:** Acetabular System

**Classification Name:**

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

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

OQG—Prosthesis, hip, semi-constrained, metal/polymer + additive, porous uncemented (21 CFR 888.3358)

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)

OQH—Hip, semi-constrained, cemented, metal/polymer + additive, cemented (21 CFR 888.3350)

OQI—Hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented (21 CFR 888.3353)

PBI—Prosthesis, hip, constrained, cemented or uncemented, metal/polymer, + additive (21 CFR 888.3310)

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Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

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**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**

Acetabular Shells:
Porous Plasma Spray (PPS®) RingLoc®+ Acetabular System, K093235 (Biomet)
Reflection Acetabular Cup System, K033442 (Smith and Nephew)
Continuum Acetabular System, K103662 (Zimmer)

Acetabular Liners:
Ringloc® E1® Acetabular Liners, K093549 (Biomet)
Reflection Acetabular Cup System, K033442 (Smith and Nephew)
Continuum Acetabular System, K103662 (Zimmer)

Constrained Heads and Liners:
Freedom Constrained Liners, K043537 (Biomet)
Cobalt Chrome Femoral Heads:
Cobalt Chrome Femoral Components, K911684 (Biomet)

**Device Description:**

The G7™ Acetabular System is a modular system, designed to provide numerous options for surgeons and patients in one compatible system. The titanium alloy (ASTM F136) shell is available in both a solid shell and limited hole design, with an apical hole and plug. The outer diameter of the shells is coated with Biomet's Porous Plasma Spray (ASTM F1580). The acetabular liners are manufactured from UHMWPE (ASTM F648) as ArComXL® or E1® (UHMWPE infused with vitamin E) and available in a Neutral, High Wall, or Ten Degree Face Changing design. Additionally, the system has provided for a constrained liner and head when such an option is required. The Biomet *Freedom*™ product line has added a 32mm *Freedom*™ head (cobalt chrome, ASTM F1537) to its offerings, as well as a new series of constrained liners (E1®, ASTM F648) designed for compatibility with the G7™ shells. A new line of cobalt chrome (ASTM F1537) femoral heads in varying sizes and neck lengths, with either a Type 1 or 12/14 taper, has been added to the system. The system is compatible with Biomet® ceramic heads and femoral stems.

## 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 by other techniques.
5. Revision procedures where other treatment or devices have failed.

Acetabular shells and femoral stems with porous coatings are indicated for uncemented biological fixation. Non-coated or polyethylene components may be used with mating components that are indicated for either cemented or uncemented use.

Indications for Biomet G7™ *Freedom*™ Constrained Liners:
The Biomet G7™ *Freedom*™ Constrained Liner is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability, and for whom all other options to constrained acetabular components have been considered.

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**Summary of Technologies:**

The technological characteristics of the proposed device are the same as or similar to the predicates. The G7™ acetabular shells are similar in design, dimensions, and intended use to their Biomet predicate, K093235, but have incorporated a different locking mechanism, which is also similar to legally marketed predicates, K091508 and K103662. The acetabular liners are made of the same material as their predicates, and use previously cleared liner types, sizes and designs. The additional constrained head is a line extension to the Biomet *Freedom™* constrained heads, and the constrained liners use the same design principles as the Freedom liner predicate, K030047. The cobalt chrome femoral heads are very similar to the Biomet predicate, K911684.

**Non-Clinical Testing:**

The following testing has been completed to support substantial equivalence:

- Poly Push Out
- Poly Lever Out
- Poly Torque Out
- Poly Rim Impingement
- Poly Deformed Cup Push Out
- Poly Deformed Cup Lever Out
- Poly Fatigue, Lever Out
- Poly Constrained Liner Rim Impingement and Lever Out Testing
- Range-of-Motion Study (Poly)
- Poly Deformed Cup Push In
- Freedom Head Pull Out of Constrained Liner
- Screw Pull Through
- Screw Torsional Properties
- Torque Curve for MIM Screw Hole Plugs
- Verification of Insertion Torque and Measurement of Torque Out

Justifications:

- Poly Wear Simulator
- Metal Head Justification
- MRI Justification
- Metal Head Axial Head Pull Off
- Metal Head Fretting/Corrosion

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

Testing demonstrates that the modifications made to the G7™ Acetabular System do not introduce any new risks of safety or efficacy, and that the G7™ Acetabular System is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 23, 2012

Biomet Manufacturing Corporation
% Ms. Becky Earl
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587 US

Re: K121874
Trade/Device Name: G7™ acetabular system
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: PBI, LPH, LZO, OQG, KWZ, JDI, OQH, OQI
Dated: October 19, 2012
Received: October 22, 2012

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,

Erin I. Keith

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): K121874

Device Name: G7™ Acetabular System

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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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K121874