



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

Biomet, Incorporated  
Ms. Becky Earl  
Senior Regulatory Specialist  
56 East Bell Drive  
Warsaw, Indiana 46581

February 10, 2015

Re: K142882

Trade/Device Name: G7 Freedom and Offset Liners, Freedom Head, Size 32

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, LZ0, OQG, KWZ, JDI, OQI, PBI, OQH

Dated: January 6, 2015

Received: January 8, 2015

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 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)

K142882

Device Name

G7 Freedom and Offset Liners, Freedom Head, Size 32

Indications for Use (Describe)

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.

Porous acetabular shells and femoral stems 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.

Additional 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.

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 G7 Freedom and Offset Liners, Freedom Head, Size 32, 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, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581  
Establishment Registration Number: 1825034

**Contact:** Becky Earl  
Senior Regulatory Affairs Specialist

**Date:** September 30, 2014

**Subject Device:** Trade Name: G7 Freedom and Offset Liners, Freedom Head,  
Size 32

Common Name: Offset and constrained acetabular liners, and femoral head.

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)

**Legally marketed devices to which substantial equivalence is claimed:**

- K121874, G7 Acetabular System, Biomet, Inc.
- K030047, K043537 Ringloc Freedom Constrained Liners, Biomet, Inc.
- K870271 S-ROM Poly Dial Constrained Socket for Acetabular Cup, Joint Medical Products (now owned by DePuy)

**Device Description**

The G7 Acetabular System is a modular system, designed to provide numerous options for surgeons and patients in one compatible system. Further liner options are being added to the G7 Acetabular System which include: Neutral +5mm liner in ArComXL or E1; G7 Freedom Constrained Liners in two new profiles, the +5mm and the 10 Degree in E1, as well as a line extension to include G7 Freedom Neutral Liners in a size 32mm; and a new Femoral Constrained Head in Size 32mm (Cobalt Chrome, ASTM F1537).

**Intended Use and 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.
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**Summary of Technological Characteristics**

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

- **Intended Use:** The proposed G7 Freedom and Offset Liners, Freedom Head, Size 32 devices have the same intended use.
- **Indications for Use:** The proposed G7 Freedom and Offset Liners, Freedom Head, Size 32 devices have the same indications for use.
- **Materials:** The proposed acetabular liners are manufactured from UHMWPE per ASTM F648. The proposed acetabular liners in both ArComXL and E1 utilize the same material and manufacturing processes as the predicate liners in K121874,

the G7 Acetabular System. The constrained liners incorporate the use of titanium alloy (ASTM F136) constraining rings, identical to the predicates. The Freedom Head, Size 32, is manufactured from wrought cobalt chrome, ASTM F1537.

- **Design Features:** The design features of the proposed liners are the same as those of the Biomet predicates and similar to the S-ROM Constrained Liners. The Freedom Head, Size 32, is similar to the previously cleared size 36 Freedom Head, with the exception of a design change to the circumferential flats to accommodate the smaller size.
- **Sterilization:** The proposed devices and the predicates are provided sterile via the same sterilization methods for single use.

#### **Summary of Performance Data (Nonclinical and/or Clinical)**

The mechanical tests and engineering analyses demonstrate the G7 Freedom and Offset Liners, Freedom Head, Size 32, are substantially equivalent to the predicate devices. No animal or clinical testing was required to support substantial equivalence. A description of the tests is located below.

- Axial Pull-out Test (Freedom Head)
- Lever-out Test (Freedom Head)
- Vertical Load Fatigue Test (Poly Liners)

Since the internal design, materials and locking mechanism of the acetabular liners are the same as the G7 liners cleared in K121874, the non-clinical testing submitted for K121874 can be used as justification for the performance of the new G7 liners.

#### **Substantial Equivalence Conclusion**

The proposed G7 Freedom and Offset Liners and the Freedom Head, Size 32mm, have the same intended use and identical or similar indications for use as the predicate devices. Performance test data and analyses demonstrate the devices to be as safe and effective as the legally marketed predicate devices, indicating the G7 Freedom and Offset Liners and the Freedom Head, Size 32mm, substantially equivalent to the predicates.